The University of New Mexico Health Sciences Center
Consent to Participate in Research
Zuni MICRA Project
Phase II

Introduction

I am being invited to participate in a research study that is being conducted by the University of New Mexico (UNM) Department of Psychology, in partnership with the Zuni Tribe through the Zuni Recovery Center, and sponsored by the National Institute of Drug Abuse. The Principal Investigators are Kamilla Venner, Ph.D. (Project Director), a Clinical Psychologist, and Robert Currier, Psy.D., Clinical Psychologist and Co-Principal Investigator, from the Zuni Recovery Center (ZRC). The purpose of this research is to study better ways to treat substance abuse and address sexual risk behaviors and sexually transmitted diseases (STDs)/HIV.

Previous studies have shown that Motivational Interviewing and the Community Reinforcement Approach (MICRA) are effective in engaging clients to learn and re-learn various skills needed to help deal with substance abuse. Motivational Interviewing (MI) is a process in which respectful communication occurs between the therapist and the client. The Community Reinforcment Approach (CRA) assists clients to find resources within the Zuni community to aid in retaining sobriety and learn skills to avoid relapse. In previous research studies, a number of research participants have had both of these interventions for the treatment of substance abuse. While both of these treatments have worked successfully with minority populations, MI and CRA have not been tried with a Native American population.

This research study is set up in two phases. The first phase of the study was to design this treatment (called MICRA) for the Zuni community. Zuni therapists and researchers from the University Of New Mexico worked together to develop this approach which we think will be helpful in treating substance abuse while addressing STDs/HIV and sexual risk behaviors. The MICRA team has tested the treatment with 9 participants looking to see if the design needed any changes. This development and testing was called Phase I. The next Phase of this study is called Phase II; a total of 80 Zuni people will participate in this Phase.

I am being invited to participate in Phase II of this study because I am seeking treatment at the Zuni Recovery Center.

This form explains the research study's possible risks as well as the benefits to me. I am encouraged to talk with my family and friends before I decide to take part in this research study. If I have any immediate questions, I may ask one of the study investigators.

What will happen if I decide to participate?

If I agree to participate, the following process will begin:

- CONSENT FORMS: Before I participate I must sign the consent and HIPPA forms which give my permission to use the information collected in this study.

- RANDOMIZATION: I will be randomized into one of two treatments groups. This means I have a 50/50 chance of being assigned to the Zuni Recovery Center (ZRC) group or to what we call the Experimental Group. The Experimental group receives the new treatment (MICRA). The ZRC group receives the treatment that ZRC normally gives to its clients.

- INTERVIEW: Regardless of which group I am assigned to, I will be interviewed about my drinking and substance use history, sexual practices, and my feelings about myself. I will be asked to fill out different questionnaires that ask questions such as "Are you feeling depressed today?" or "Do you have trouble sleeping?" I will be interviewed when I start the project, and I will be interviewed at four, eight, and 12 months after my first interview (Follow-up visits). The same types of questions will be asked at each follow-up visit. The questionnaires and the interviews will be done at the project office and will take approximately 6 – 8 hours to complete. The interviews will occur over the course of several days. We will work to make sure all interviews will be completed within a week. To schedule the follow-up interviews, you may be contacted by text message or telephone, or visited at your home. If you prefer not to be contacted through a particular method, please let us know and we will respect your wishes.

- TESTING:

1. Saliva Drug Test: Regardless of which group I am assigned to, I will be asked to give saliva to test for drug use at the start of treatment, and at the 4 month, 8 month, and 12 month follow-up visits. The results from the drug testing will be given to me if I so request. The saliva samples are sent to a lab in Virginia, and no identifying information other than my study ID number will be included with the sample. No saliva samples are kept for future testing or future research. These drug test results will not be shared with Tribal Courts or any other tribal program without my written permission.

2. Breathalyzer Test: Regardless of which group I am assigned to, I will also be asked to do an alcohol breathalyzer in order to monitor alcohol use at different times during my participation in the study. The results from the alcohol breathalyzer will be given to me if I so request but will not be shared with the Tribal Courts or any other tribal program without my written permission.

- DECLINING TO ANSWER A QUESTION OR A TEST: Regardless of which group I am assigned to, I may decline to answer any question on any test, and I can decline to take any drug or alcohol test. If I so decline the alcohol or drug test I may be asked to leave the study. If I am asked to leave the study, I will be referred to ZRC's normal intake process so that I may continue to receive treatment.

- COURT COMPLIANCE FOR TREATMENT: If I am court-ordered for substance abuse treatment and I leave the study either by request or by decision of the PI, the MICRA team has no control over type of treatment and time required by ZRC for treatment. I am still responsible for complying with my court order. The time spent in treatment with the MICRA project does not "carry over" to ZRC or to any other facility.

- AUDIO RECORDING OF THERAPY SESSIONS: Regardless of which group I am assigned to, my sessions with the therapists will be audio taped in order to provide training and feedback to the therapists. My therapist will encrypt (make secure) the audio recording using MEO

Encryption software before sending recordings to the UNM trainers and coders. These audio tapes will be coded by a master's level therapist who works at UNM, or the tapes might be coded by the PI. The tapes might also be coded by a graduate student who works at UNM. The coding is not done to code any personal information. The tapes will be transcribed during the course of my treatment and at the end of the project. The end of project will occur approximately 3 years after my treatment. The purpose of the coding at the end of the project (second coding) is to ensure that the first coding was correct. All tapes will be destroyed after the second coding.

How long will I be in this study?

Participation in this study is estimated to take about 30 hours over a period of 12 months.

What are the risks or side effects of being in this study?

- Participation in this study may involve some risks including inconvenience, loss of privacy and possible loss of confidentiality. Also, I may feel uncomfortable answering some questions and I may feel stress or some emotional discomfort/distress from participating in this study. I may choose to not answer any question at any time. In researching these two treatments, Motivational Interviewing and Community Reinforcement Approach, we have not encountered any additional risks other than stress and emotional discomfort.

- **Randomization risks:** I will be assigned to a treatment group by chance. The treatment I receive from the experimental group may prove to be less effective than what ZRC already offers for treatment and it may prove to be less effective than other types of available treatment.

- **What are the benefits to being in this study?**

I may or may not benefit from participating in this study. However, it is hoped that information gained from this study will help in the future treatment of Native Americans with substance abuse problems.

What other choices do I have if I do not want to be in this study?

I do not have to participate in this study to receive treatment for substance abuse. If I choose not to participate in this study, I may receive treatment at ZRC, or I may receive treatment at the Indian Health Service Hospital.

How will my information be kept confidential?

The MICRA team will take measures to protect my privacy and the security of all my personal information, but they cannot guarantee confidentiality of all study data.

Information contained in my study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human participant research, and the National

Institute on Drug Abuse will be permitted to access my records. There may be times when the MICRA team is required by law to share my information. However, my name will not be used in any published reports about this study.

To help the MICRA team further protect the confidentiality of my data, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify me in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however upon request of DHHS or other federal agencies for audit or program evaluation purposes.

I should understand that a Confidentiality Certificate does not prevent me from voluntarily releasing information about myself or my involvement in this research. Note however, that if an insurer or employer learns about my participation, and obtains my consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that I must also actively protect my own privacy and the confidentiality of my data.

Finally, I should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm of myself or others.

What are the costs of taking part in this study?

I will not be charged for any study procedures or treatments.

What will happen if I am injured or become sick because I took part in this study?

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study. If I am injured or become sick as a result of this study, UNMHSC will provide me with emergency treatment, at my cost. It is important for me to tell the MICRA staff or investigators immediately if I have been injured or become sick because of taking part in this study. If I have any questions about these issues, or believe that I have been treated carelessly in the study, I should contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

At baseline interview, a gift certificate of $50 as compensation for my time will be given.

$50 will be given for each follow-up interview at 4, 8, and 12 months.

If I withdraw from the study, I will receive no compensation other than that which I have already received.

How will I know if you learn something new that may change my mind about participating?

I will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change my mind about participating.

Can I stop being in the study once I begin?

My participation in this study is completely voluntary. I have the right to choose not to participate or to withdraw my participation at any point in this study without affecting my future health care or other services to which I am entitled.

If I am court-ordered for substance abuse treatment, and I do leave the study, I am still responsible for complying with my court order. The time spent in treatment with MICRA does not "carry over" to another treatment facility.

If my substance abuse escalates and the Program Coordinator decides I need more intensive treatment, every effort, in conjunction with ZRC, will be made to refer me to a program where I can get the necessary treatment. Ending treatment participation does not mean I am withdrawn from the research interviews – I will still be contacted unless I tell the MICRA staff that I do not want to be a part of the research study anymore.

When will the research forms I complete be destroyed?

The research forms will be destroyed five years after tribally-approved publications have been completed.

Who can I call with questions or complaints about this study?

If I have any questions, concerns or complaints at any time about the research study, Dr. Kamilla Venner, Ph.D., or her associates will be glad to answer them at (505) 925-2377 at any time. I may also speak with Dr. Robert Currier at (505) 782-4717. If I would like to speak with someone other than the research team, I may call the UNMHSC HRRC at (505) 272-1129. I may also phone a Zuni community member who is not connected to this research project such as Terry Kanesta-Brislin at (505) 782-7302 or Carmelita Sanchez at (505) 782-2343 if I have any questions about my rights as a research participant or feel I have not been treated well.

Who can I call with questions about my rights as a research participant?

If I have questions regarding my rights as a research subject, I may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, I may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

Consent

I am making a decision whether to participate in this study. My signature below indicates that I have read the information provided (or the information was read to me). By signing this consent form, I am not waiving any of my legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to me.

_____	_____/_____
Name of Adult Participant (type or print)	Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____	_____/ _____
Name of Research Team Member	Signature of Research Team Member Date

I have translated parts of this consent form for the participant from English into Zuni.

_____	_____/_____
Name of Translator	Signature of Translator Date