Research to Reduce Time to Treatment for Heart Attack/Myocardial Infarction for Rural American Indians/Alaska Natives (AI/AN)

Attachment 9B

Consent Form for the Medical Care Providers Interview

Missouri Breaks Industries Research, Inc.
Informed Consent to Participate in a Research Study
Medical provider consent form
11th Grade Reading Level – Fry Readability Method

Study Title: Time to Reduce Treatment for Heart Attacks in American Indians / Alaskan Natives (AI/AN)

A. PURPOSE AND BACKGROUND

The intent of the heart attack to treatment project is to work with community members who are directly affected by the increasing rates of heart disease and heart attacks in our American Indian communities and to better understand how to design educational messages that will reduce the time to treatment for heart attacks. It is the goal of this process to identify both a better message and mode of delivery that will improve community awareness and thus improve heart attack outcomes.

This research is being sponsored by the Centers for Disease Control and Prevention (CDC). Missouri Breaks Ind. Research Inc. (MBIRI) an American Indian owned company based out of the Dakotas is conducting it. You are one of about 54 people being asked to participate in the medical providers section of this study. Other sections of this study include a group of individuals who have had a heart attack, a community leader group, a focus group of individuals who have experienced a heart attack and a focus group of individuals who are at high risk for having a heart attack.

B. PROCEDURES

If you agree to take part in this research study, the following will occur:

- You will be interviewed for about thirty to sixty minutes about your perceptions of the barriers that prevent people from receiving early treatment for heart attacks.
- The interview will be audio taped to ensure accuracy in reporting your statements.
- The interview will take place by phone at a time that works best for you. You will be sent a consent form along with a copy of the questionnaire for your review prior to the call. Once we receive your signed consent form back we will call you to set up a time for the interview.
- The researcher may contact you later to clarify your interview answers.
- Total time commitment will be two hours.

C. RISKS

There is a low risk of loss of privacy. Every effort will be made to protect your information. No names or identities will be used in any published reports of the research. There may be a small risk of discomfort or anxiety due to the nature of the questions asked; however, you may choose to answer only those questions that you choose to, and can stop participation in the research at any time.

D. **CONFIDENTIALITY**

The research data will be kept in a secure location, and only the researchers will have access to the data. At the conclusion of the study, all identifying information will be removed and
the data will be kept in a locked cabinet at the MBIRI offices. Audiotapes will be destroyed at the end of the study.

E. **DIRECT BENEFITS**

You will receive no direct benefits for participating in this interview other than the satisfaction of contributing to the understanding of what can be done to reduce the time to treatment for heart attacks among rural Native Americans.

F. **COSTS**

There will be no cost to you for participating in this research.

G. **COMPENSATION**

Upon completion of the interview process, each Individual Key Informant will be provided with a $10.00 Visa gift card.

I. **PROBLEMS OR QUESTIONS**

Should any problems arise from this project or if you have any questions about this study you should contact the Project Officer Dr. Nell Brownstein at the Center for Disease Control at 770 488-2570 Monday through Friday from 8 am to 5 pm Eastern time, or Marcia O'Leary RN (mol@mbiri.com), Melissa O'Leary RN (makunf@mbiri.com) or Sue Sherwood (ssherwood@mbiri.com), Missouri Breaks Ind. Research Inc. at 1-866-865-3418 Monday through Friday from 8 am to 5 pm Mountain time.

J. **STOPPING THE STUDY**

You have the right to refuse any of the questions that you are not familiar with or are uncomfortable with. We hope that you will answer as many of the questions as possible.

K. **PARTICIPANTS' RIGHTS**

Questions about your rights as a study participant, or comments or complaints about the study, may also be addressed to the Office for the Protection of Human Subjects, Carma Ayala, Ph.D. at 770-488-4572, Monday through Friday from 8 am to 5 pm Eastern Time. You may contact
_____ at your regional IRB about your rights as a research participant. (this contact name will be filled in once the regional IRB approves the study and identifies that contact person from their region)

L. **RESPONSIBILITY FOR THE STUDY**

Missouri Breaks Industries Research Inc. has taken responsibility for this project. Signing the consent form will let the Missouri Breaks staff with the oversight of the

project officer from the CDC, conduct the interviews and review the material. MBIRI will then develop materials about the signs of a heart attack and about the importance of people getting immediate medical treatment for themselves or other members of the community who have had a heart attack.

M. **CONSENT TO PARTICIPATE**

I have read this consent form and I have had an opportunity to talk about it and to ask questions. I understand what it says and that I can ask questions at any time. After thinking about the risk and benefits that I learned about in the Information and Consent Form, I want to join this research project. I understand that a copy of this consent form will be given to me for my records.

PARTICIPATION IN THIS RESEARCH IS VOLUNTARY. You are free to decline to participate in this research study, or to withdraw your participation at any point, without penalty.

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Adult Participant Date