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

Attachment 7B

Consent Form for AI/AN Community Leaders Interview

Missouri Breaks Industries Research, Inc.
Informed Consent to Participate in a Research Study
Community Leader consent form
8th Grade Reading Level - Fry Readability Method

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

A. PURPOSE AND BACKGROUND

The intent of this heart attack 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 help community members survive heart attacks. Our goal is to find both a better message, and messengers, and a better way of delivering a message that will improve community awareness about the signs of heart attack and the need to call 9-1-1 right away. When community members act faster the result will be better outcomes for people who have heart attacks.

This research is being sponsored by the Centers for Disease Control and Prevention (CDC). It is being conducted by Missouri Breaks Ind. Research Inc. (MBIRI) an American Indian owned company based out of the Dakotas. You are one of about 30 people being asked to take part in the community member section of this study. Other sections of this study include a group of medical providers; a group of individuals who have had a heart attack, a focus group of individuals who have had 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, this is what will happen:

- You will be interviewed for about thirty minutes about what you think is the communities' general understanding of the signs or symptoms of a heart attack and what they would do if they think someone is having a heart attack.
- The interview will be audio taped so we record exactly what you said.
- The interview will take place by phone at a time that works best for you. Before the call, we will send you a consent form and a copy of the questions that we will ask you. Please read the questions and sign the consent form. Once you send back your signed form, we will call you to set up a time to talk.
- We may contact you later if we do not understand any of your answers to the questions.
- The interview will take 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 is a small risk of discomfort or anxiety due to the nature of the questions asked; however, you can answer only those questions you choose to answer, and can stop the interview at any time.

D. **CONFIDENTIALITY**

The research data will be kept in a secure location, and only the researcher will have access to the **data. At the end 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 taking part 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.

H. **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, Melissa O'Leary RN or Sue Sherwood, Missouri Breaks Ind. Research Inc. at 1-866-865-3418 Monday through Friday from 8 am to 5 pm Mountain time.

I. **STOPPING THE STUDY**

You have the right to refuse to answer 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.

J. **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, 8 am to 5 pm Eastern time. You may contact _____ at your local 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)

K. **RESPONSIBILITY FOR THE STUDY**

Missouri Breaks Industries Research Inc. (MBIRI) has takes responsibility for this project. Signing the consent form will let the MBIRI staff, with oversight by the project officer from the CDC, carry out the interviews and review the material. Then MBIRI will 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.

L. **CONSENT TO PARTICIPATE**

I have read or had read to me, this consent form and I have had a chance 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