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

Attachment 6B

Supplementary Materials for the Focus Group Discussion Involving Participants at High Risk of MI (no Prior History of MI)

1) **Draft Agenda**
2) **Consent Form**

Draft Agenda
Participants at High Risk of MI
(no Prior History of MI)

8:00 am - **Opening/introduction**

8:15 am - **Getting started – meeting the participants**

8:45 am - **Knowledge, attitudes, awareness of symptoms**

9:30 am – **Responding to signs and symptoms**

10:00am - **Break**

10:15 am - **Information and education**

10:45 am - **Barriers**

11:15 am - **Systems**

11:30 **Break for Lunch**

1:00-2:30 pm **Reactions to concept statements and drafted educational messages**

The ideas from the morning discussion will be integrated with interviews and the MI focus group results, and will be presented for consideration and feedback by the group These non-MI individuals will be asked to review the messages and visual content that have been developed through the combination of interviews and the MI focus group opinions and to further help refine the messages and visual materials.

Missouri Breaks Industries Research, Inc.
Informed Consent to Take Part in a Research Study
As a focus group participant consent form
8th 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 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 to better understand and plan educational messages that will help community members survive heart attacks. Our goal is to find both a better message and a better way of delivering a message that will improve community recognition 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 funded 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 8 - 12 people being asked to take part in one of two focus group sections of this study. Other sections of this study include: 1. A group of medical providers; 2. A group of individuals who have had a heart attack or at risk for having a heart attack and 3. A group of community members who are familiar with the community.

B. PROCEDURES

If you agree to take part in this research project, this is what will happen:

- You will be asked to travel to a central location where the focus group will be held. The project will pay for the cost of your airline ticket, lodging, meals and will give you an allowance for your time.
- You will be asked to take part in a focus group retreat for around six hours about your view regarding time to treatment of heart attack and then later in the day you will be asked to look at and give your view of some possible ideas that come out of this discussion.
- The interview will be audio taped to guarantee correctness in reporting your statements.
- The researcher may need to contact you later to better understand your interview answers.
- Total time commitment will be six hours which will not include travel time.

C. RISKS

There is a slight 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 unease due to the nature of the questions

asked; however, you can answer only those questions you choose to answer, and you can stop taking part in the research at any time.

D. **CONFIDENTIALITY**

Because the focus group includes discussions of personal views, extra safety measures will be taken to protect your privacy. The research will begin in the focus group by asking the participants to agree to the value of keeping information discussed in the focus group private. In recognition of tribal diversity, study participants will represent three AI/AN regions of the U.S. **In the group conversation, members will be known by first name only. The study members will then be asked to agree out loud to keep the group conversation private and then will be reminded at the end of the group conversation to keep the names of each member and the conversation private. The research data will be kept in a safe place, and only the researcher will have access to the data. At the end of the study, any information about you will be removed and the data will be kept in a locked cabinet at the MBIRI offices. Audio tapes 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 project.

G. **COMPENSATION**

You will receive $100.00 for your time in addition to your flight, motel and meal expenses.

H. **PROBLEMS OR QUESTIONS**

Should any problems take place 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 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 8 am to 5 pm Mountain time.

I. **STOPPING THE STUDY**

You have the right to refuse any of the questions that you do not understand 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 member, 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 local IRB about your rights as a research study member. (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. is responsible to complete this project. Signing the consent form will let the Missouri Breaks staff under the skilled direction of the project officer from the CDC, carry out the interviews, review and evaluate the interviews then use the data to help us make educational messages about the importance of reducing the heart attack to treatment time.

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 is says and that I can ask questions at any time. After thinking about the risk and benefits that I learned about in this consent form, I want to take part in this research project. I understand that a copy of this consent form will be given to me for my records.

TAKING PART IN THIS PROJECT IS VOLUNTARY. You are free to decline to take part in this research study, or to withdraw your involvement at any point, without penalty.

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Adult Participant Date