DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

DATE: June 6, 2008

FROM: IRB Administrator
Human Research Protection Office
Office of Scientific Regulatory Services
Office of the Chief Science Officer, CDC

SUBJECT: CDC Approval of Exemption for CDC Protocol #5435, "Research To Reduce Time To Treatment For MI (Myocardial Infarction) For Rural American Indians/Alaska"

TO: J. Nell Brownstein
NCCDPHP

On behalf of the CDC Human Research Protection Office (HRPO), I have reviewed the request to exempt protocol #5435, "Research To Reduce Time To Treatment For MI For Rural American Indians/Alaska", and find that this research activity is exempt under 45 CFR 46.101(b)(4). This determination is valid for a period of three years (through 6/6/2011). However, we strongly encourage investigators to close out exempt protocols as soon as CDC staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Please be aware that changes to this protocol may not be implemented until they are reviewed by HRPO and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised that investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact your Division Associate Director for Science, your National Center Human Subjects Contact, or HRPO at Human Subjects Review – OD on the CDC global address list, huma@cdc.gov, or by telephone at 404-639-4721.

Constance M. Bonds, MPA
IRB Administrator, Assurances and Reliance Relationships
Centers for Disease Control, Office of the Chief Science Officer
Human Research Protection Office
1600 Clifton Rd. NE, M/S D-73
Atlanta, GA. 30033
Phone: (404) 639-4967 Fax: (404) 638-5333

cc:
Joan Redmond-Leonard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Indian Health Service
Research Program
801 Thompson Avenue
Rockville, MD 20852

February 8, 2008

Marcia O'Leary
Project Coordinator
Missouri Breaks Industries Research
HCR 64, Box 52
Timber Lake, South Dakota 57656

RE: **"Research to Reduce Time to Treatment for MI for Rural American Indians/Alaskan Natives (AI/AN)" #N07-N-07-EXEMPT.**

Dear Ms. O'Leary:

Members of the Indian Health Service (IHS) National Institutional Review Board (NIRB) have reviewed your project **"to Reduce Time to Treatment for MI for Rural American Indians/Alaskan Natives (AI/AN)"**, a national project involving interviews and focus groups.

Based on our review of the material you submitted, we found that this focus group/interview protocol is **EXEMPT** from the requirement for further NIRB review under 45 CFR 46.101(b)(2). This decision is based on the information provided by you which shows:

- Use only of surveys, interview procedures and focus groups; and
- No disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

The NIRB conducts primary reviews for the Bemidji, Tucson, Albuquerque and California Areas of the IHS. You may proceed with your protocol in these areas. Since the NIRB has found this project to be exempt from the requirements of 45 CFR 46, annual renewal of the protocol by the NIRB will not be required. However, any proposed changes to your protocol should be prospectively approved by NIRB staff. Also, publications resulting from this project should be cleared through the NIRB prior to submission.

If you have any questions about this IHS NIRB review or decision, please contact me at (301)443-1549, or Dr. Alan Trachtenberg, Human Research Protection Administrator at (301)443-0578.

You may also email the IRB at IRB@IHS.gov. All official correspondence should also be sent by US mail, marked prominently with your study # and mailed to IHS-NIRB, c/o Ms. Mary Eve Mahsetky, Office of Public Health Support, 801 Thompson Ave., TMP 450, Rockville, MD 20852. We appreciate your interest in research to provide rural AI/AN with the benefits of a more rapid response time for cardiac emergencies.

Sincerely,

Phillip L. Smith, MD, MPH
Chair, IHS National IRB
IRB00000646
FWA00008894

CC: J. Nell Brownstein, Ph.D.

ABERDEEN AREA IRB/RESEARCH and PUBLICATION COMMITTEE

Aberdeen Area IRB
Indian Health Service
Room 309
115 – 4th Ave. SE
Aberdeen, SD 57401
Toll Free #: (866) 331-5794

November 29, 2007

Marcia O'Leary
Missouri Breaks Industries Research Inc.
HCR 64, Box 52
Timber Lake, SD 57656

AAIRB #: 07-R-13AA

Dear Ms. O'Leary,

The Aberdeen Area Institutional Review Board (AAIRB) has reviewed the information you submitted fulfilling the conditions set for protocol 07-R-13AA "Research to Reduce Time to Treatment for MI for Rural American Indians/Alaskan Natives (AI/AN)."

This is to confirm that your protocol is approved. Please be aware that according to the publication approval process, *the AAIRB has final approval of ALL publications related to this project*. You are granted permission to conduct your study, as most recently described, effective immediately. The study is subject to continuing review on or before **September 21, 2008**, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review. This approval does *not* cover any fliers or presentations (oral, poster, or handouts) that may be made regarding this study. Presentations will need a separate AAIRB approval and Service Unit/Tribal approvals if necessary. Contact Marsha Remleitner, AAIRB Coordinator, at (605) 226-7493 if you have any questions or require further information.

Sincerely,

Elaine Miller MD

Elaine Miller, MD
Co-Chairperson, AAIRB

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Oglala Sioux Tribe
HEALTH ADMINISTRATION
P.O. Box 5011 Pine Ridge, So. Dakota 57770
Ph. 605.867.1704 Fax 605.867.2063

Oglala Sioux Tribe Research Review Board

May 9, 2008

Marcia O'Leary
Missouri Breaks Industries Research Inc.
HCR 64, Box 52
Timber Lake, SD 57656

Re: Continued Approval for Research to Reduce Time to Treatment for MI for Rural American Indians/Alaskan Natives (AI/AN)

Dear Ms. O'Leary:

On May 9, 2008, the Oglala Sioux Tribe Research Review Board (OSTRRB) reviewed the revised research proposal entitled, "Research to Reduce Time to Treatment for MI for Rural American Indians/Alaskan." This study is to identify a better message and messenger or mode of delivery that will improve community awareness of the signs and symptoms of Myocardial Infarctions and the need to seek appropriate and immediate health care.

This approval is for a period of one year from the date of this letter and will require continuation approval if the research project extends beyond **May 9, 2009**.

If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the OSTRRB for approval before implementing the changes. Furthermore, if the results of the research are used to prepare papers for publication or oral presentations at professional conferences, manuscripts or abstracts must be submitted to the OSTRRB for pre-publication approval. Final results and a semi-annual report should be presented to the OSTRRB at a regular session meeting. Our meetings are set for the second Friday of each month. The location is TBA, therefore you should contact the OSTRRB Coordinator at our office to request further information and placement on the agenda.

We appreciate your interest in providing the benefits of health research to the Oglala Sioux Tribe and our members. If you have any questions regarding the OSTRRB's decision, please contact our OSTRRB Coordinator.

Sincerely,

Lisa Schrader-Dillon, M.S.W.

Lisa Schrader-Dillon, MSW
Health Administrator

Cc: OSTRRB file

December 18, 2007

Marcia O'Leary
Project Coordinator
Missouri Breaks Industries Research
HCR 64, Box 52
Timber Lake, South Dakota 57656

Dear Ms. O'Leary:
During the November 20, 2007 meeting of the Alaska Area IRB the committee reviewed the protocol and all accompanying documents of the project titled: **2007-10-034 Research to Reduce Time to Treatment for MI for Rural American Indians / Alaskan Natives (AI/AN).** The Alaska Area Institutional Review Board (AAIRB) has the following comments for the investigators:

1. The project is less than minimal risk.
2. The investigators should note that a call to 9-1-1 in the villages of Alaska will not generate an emergency medical services (EMS) response in all cases.
3. The IRB would like the investigators to tell the IRB when the links to the interviews and to the tapes will be destroyed.
4. The responses cannot be directly connected to an individual.
5. The telephone interviews will be assigned a link that will be destroyed after the data are entered.
6. The Alaska Area IRB is not "the Juneau IRB", but we are the Alaska Area IRB located on the Alaska Native Health Campus in Anchorage, Alaska.

The protocol qualifies for research that is exempt from IRB review per 45 CFR 46.101(b)(4). Tribal approval is required in addition to IRB approval. As a reminder, the protocol and all accompanying documents **may not have modifications** for this decision to remain valid. It is your responsibility as Principal Investigator (PI) to maintain the status of your project by tracking, and monitoring all activities related to the protocol.

All research approved by the Alaska Area IRB is subject to 45 CFR 46 "Protection of Human Subjects" regulations and the principles of the Belmont Report. Investigators are expected to be familiar with these provisions and adhere strictly to all requirements. You are required to have all personnel involved in the research complete the training at www.citiprogram.org, once every 36 months. Please retain your completion certificates from the Collaborative IRB Training Institute (CITI).

This IRB action does not constitute review or compliance with HIPAA requirements. Prior to access and/or use of data, you must receive approval from the appropriate institutional officials releasing this information under the current HIPAA requirements.

All research involving staff, patients or resources at the Alaska Native Medical Center (ANMC) must be submitted to the Board(s) of Directors of ANMC's parent organizations after Alaska Area Institutional Review Board approval is obtained. The parent organizations of ANMC are the Southcentral Foundation (SCF) and the Alaska Native Tribal Health Consortium (ANTHC). Your point of contact at ANTHC is Kathy Koller, RN, MSN at kkoller@anmc.org. Your point of contact at SCF is Dr. Ruth Etzel at raetzel@southcentralfoundation.com. Please send a copy of your approved research protocol and a copy of the Alaska Area IRB approval letter to each of them. In addition all research protocols must receive tribal approval.

If this protocol utilizes information from the Alaska Native Medical Center you must submit any manuscripts, reports, or abstracts for consideration for publication or presentation to the Abstracts Manuscripts and Publications Committee (AMP RC) for review. In addition the ANTHC and SCF Board of Directors approval must be obtained. To ensure timely review, please send an electronic copy of these items to both Dr. Etzel and Mrs. Koller at least 8 weeks before the deadline for submission.

If you have further questions for the Alaska Area IRB you may contact me at tjpowell@anmc.org or call (907) 729-3924 between the hours of 8:00am and 4:00pm, Monday through Thursday.

Sincerely,

Terry J. M. Powell
IRB Administrator
Alaska Area Institutional Review Board
4315 Diplomacy Drive RMCC
Anchorage, Alaska 99508