

Application for OMB Clearance

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

Supporting Statement Part A

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A. JUSTIFICATION

A.1 CIRCUMSTANCES MAKING THE INFORMATION COLLECTION NECESSARY

Every year, approximately 1.1 million Americans have their first or a recurrent heart attack/myocardial infarction (MI). About one third of these heart attacks will be fatal. Early recognition of a MI by both the victim and bystanders followed by prompt cardiac emergency and advanced care has a direct effect on patient outcomes (heart damage, morbidity and mortality): the shorter the delay to treatment, the better the outcomes. Results of a recent Behavioral Risk Factor Survey (BRFSS) survey showed that public recognition of major MI symptoms and the need for immediate action by calling 9-1-1 was poor and that there is a need for increased public health efforts.¹ Patient delay accounts for most of the lag in treatment. The longest delay (often several hours) occurs while patients are deciding whether their symptoms are significant and whether or not they should seek medical care.

The reasons for delays in treatment have been explored in a limited number of studies. Focus group findings from the 20-city Rapid Early Action for Coronary Treatment (REACT) trial showed that patients underestimate their risk, do not understand the benefits of rapid action, have rarely talked about MI and appropriate responses with their health care providers or family members, and appear to need the permission of family and providers to act.² The REACT study also attempted to reduce out-of-hospital delay time and increase Emergency Medical System (EMS) use. The intervention targeted mass media, community organizations, and professional and patient education. Although population surveys indicated there was greater public awareness and knowledge of program messages the study did not achieve a greater reduction in delay time within the intervention community group. The conclusion of the REACT investigators was that new intervention strategies are needed.³

Data from the National MI Registry suggest that the greatest disparity for time to treatment exists among racial and ethnic minorities and that the American Indian/Alaska Native (AI/AN) group has the longest delay times.⁴ However, compared to data collected on 62,883 white persons, the National MI Registry only collected data on 164 AI/ANs.⁵ AI/ANs comprise 1.5% of the U.S. population and their educational levels were below the national average in 2000.⁶ During the past several years marked increases in the prevalence of many risk factors (e.g., obesity, diabetes, high blood pressure, high blood cholesterol, physical inactivity, and smoking) for heart disease and stroke have increased among this population. Adults with diabetes are 2–4 times more likely than those without diabetes to die of heart disease or stroke. Diabetes was once rare among AI/AN people but the prevalence is rising dramatically. This population also has a heavy burden of heart disease and stroke.⁶ Heart disease death rates for the population were 20% higher than the total U.S. population by the late 1990's and stroke death rates were 14% higher.⁷ These circumstances suggest that delays in treatment for MI are of particular concern for AI/AN persons.

Specific information about treatment patterns for MI in AI/AN communities is limited. The REACT study, for example, was not conducted in rural areas or among AI/AN populations. A small pilot study of 159 patients, admitted to care facilities with MI, was conducted by the Native American Cardiology program of the IHS.⁸ The NATIVE study showed that rural

American Indians presenting with acute MI have marked delays in time to treatment (12% of patients waited between 12-24 hours and 23% waited more than 24 hours to present), thus limiting treatment options; the primary cause of the delay was due to patient misunderstandings about the symptoms of MI. There are no studies, except the small NATIVE pilot project, presenting any information about what AI/ANs understand or misunderstand about the warning signs of MI. There are no studies that present information about whether or not members of this population understand that MI is a medical emergency and that they should immediately call 9-1-1 for medical help.

CDC requests OMB approval to conduct a new, collaborative, one-time information collection to address gaps in knowledge about MI in AI/AN populations and to develop a key health message for reducing time to treatment in AI/AN populations. Respondents will be recruited from three regions of the U.S. Information about knowledge, attitudes and behaviors will be collected through interviews with key informants including medical providers, community leaders, and AI/AN community members. In addition, more detailed information will be collected through extended focus group discussions with AI/AN community members who have experienced an MI or who are considered at high risk for MI. Focus groups will be conducted in the context of a one-day retreat that will require participating respondents to travel to a central location. All study-related procedures for contacting, recruiting, and collecting information from respondents have been designed to be culturally appropriate for AI/AN populations.

The proposed study will be a collaborative effort involving participants in the Healthy 2010 Healthy People CVD Partnership. Partnership agency members include CDC; the National Heart Lung and Blood Institute (NHLBI), which includes the National Heart Attack Program; Indian Health Services (IHS); and the American Heart Association (AHA). Members of the Native American Cardiology Program, within IHS, are members of the project advisory work group. The involvement of IHS as well as AI/AN community members who are affected by heart disease will be integral to the success of the project.

CDC is authorized to collect this information by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1**).

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

This project relates to several Centers for Disease Control and Prevention (CDC) and Division of Heart Disease and Stroke Prevention (DHDSP) goals and priorities including the elimination of ethnic and geographic disparities, increasing knowledge of signs and symptoms of MI, and the need to get improved emergency treatment <http://www.cdc.gov/DHDSP/>. It will contribute to our understanding of AI/AN populations and their perceptions and misconceptions about MI and the need for immediate treatment. Reducing time to treatment can have an important public health impact on MI mortality in these populations. It supports the Public Health Action Plan <http://www.cdc.gov/DHDSP/> because the project focus is on raising community awareness and knowledge and promoting population behavioral change in order to reduce MI-mortality in a high-risk population. The proposed project supports Healthy People 2010 goals (12-1, 2) to increase the proportion of persons who are aware of the major signs and symptoms of heart

attack, to call 9-1-1 as the first action to take when someone has a heart attack, and to reduce MI-related mortality.

The information to be collected will be used to identify and design a more effective way of assisting people in understanding the appropriate response to the signs and symptoms of a heart attack. The specific aims of this proposed project are to:

- Gain an understanding of the barriers and the facilitators that impact rural American AI/AN populations' understanding of MI signs and the delays to treatment following an MI.
- Develop and produce tailored key messages and sample copy (e.g., radio, print, stories) that resonate with rural AI/AN populations.
- Identify effective methods and style of delivery for the messages.

The messages to be customized for AI/AN populations will be consistent with messages developed for the “Act In Time” action plan funded by HHS/National Heart, Lung and Blood Institute/National Heart Attack Alert Program (HHS/NHLBI/NHAP) (additional information posted at http://www.nhlbi.nih.gov/health/public/heart/mi/act_plan.pdf). The Act in Time campaign promotes three core messages to help people survive a heart attack: 1) Learn the heart attack warning signs, and act fast if you feel them; 2) Talk with family and friends about the warning signs and call 9-1-1 right away; and 3) Ask your doctor about your heart attack risk and how to lower it. However, the core messages have not been adapted in culturally appropriate ways for AI/AN populations. The proposed partnership effort will develop messages and materials to fill this gap and will thus complement and extend the current national Act in Time campaign. The overall objective is to improve MI outcomes in AI/AN populations.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

The information to be collected in this study will be qualitative (descriptive) and will not utilize electronic, computer-based, or other automated information collection methods. The majority of respondents will be interviewed by telephone.

A portion of respondents will participate in extended focus group discussions that will take place in the context of a one-day retreat. Culturally, it is important to give all participants a chance to speak and give their opinions, because a hurried interview process can be viewed as disrespectful in the American Indian culture. To provide respondents with as much time as they need, the burden estimate therefore reflects a substantial portion of the time commitment for the all-day retreat. We are collecting a minimum amount of data from a small number of people for the purposes of this project.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

We have conducted a literature search and have confirmations from IHS and NHLBI that there is no data available on the topic of this study.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

No information will be collected from small businesses.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

This is a new, one-time information collection, and without it we will not have the information needed to meet our specific aims. There are no legal obstacles to reduce the burden.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5

All guidelines are met and our request fully complies with the regulation.

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY

A.8.a Federal Register Notice

A 60-day Federal Register Notice was published in the *Federal Register* on July 31, 2007, Vol. 72, No. 146, pp. 41757-41758 (see **Attachment 2A**). Three public comments were received. The public comments and CDC's responses to them are summarized in **Attachment 2B**. One public comment concerned the extent of Tribal consultation which is described in more detail in Section A.8.b. below.

A.8.b. Efforts to Consult Outside the Agency

CDC has a long, on-going consultation with its partners of the Healthy People 2010 CVD Partnership and this is the first joint research project. Drs. Veazie, Galloway, and Brody (all from the IHS Native American Cardiology Program) participated in the planning and design of the project which began in 2005. CDC has instituted a MI project advisory workgroup consisting of representatives from the partnership agencies as well as tribal members and others (see **Attachment 3** for list of members of the advisory group for the study). The advisory workgroup has been meeting monthly since the inception of the project in 2006 and its main charge has been to develop the interview and focus group instruments. The advisory group will also review the information collected and provide feedback and recommendations with respect to potential messages.

Since August 2007, Dr. Allen Trachtenberg, Research Director at IHS and head of IHS’s national IRB (NIRB), has provided guidance for the development and implementation of the proposed project. Since 2007, we have been working with several tribes and tribal IRBs (Southwestern, Aberdeen, and Alaska regions) in order to obtain IRB approval and to meet IHS requirements for tribal consultation (see **Attachment 4**). Also, the tribal leaders that consult with CDC have requested that we consult with them, and the tribes they represent, regarding our findings. These tribes and tribal leaders will provide input which will help shape our final products. Additionally, before any products are released, we will obtain feedback from the National Indian Review Board and the tribes participating in this project.

Contact Information for IHS and National IRB Membership		
Indian Health Service and National IRB	Dr. Alan Trachtenberg IHS Human Research Protection Administrator IHS National IRB 801 Thompson Ave. TMP Suite 450 Rockville, MD 20852 (301)443-4700 Alan.Trachtenberg@ihs.gov	Eric A. Brody MD, FACC Associate Director, Native American Cardiology Program Assistant Professor, Clinical Medicine University of Arizona 1501 North Campbell Ave. PO Box 245037 Tucson, AZ 85724 Phone (520)694-7000
	Mark A. Veazie, DrPH Epidemiologist Native American Cardiology Program Indian Health Service 1215 N. Beaver St., Suite 201 Flagstaff, Arizona 86001 Voice (928)214-3921	
Alaska Area IRB	Dr. David Barrett Alaska Area IHS IRB Chair	Terry Powell Alaska Area IHS IRB Administrator 4315 Diplomacy Drive RMCC, Anchorage, Alaska 99508 (907)729-3924 tjpowell@anmc.org
Aberdeen Area IRB	Elaine Miller Aberdeen Area IHS IRB Chair Elaine.miller@ihsabr.ihs.gov	Marsha RernLeitner 115 4 th Avenue, SE Aberdeen, South Dakota 57401 (605)226-7341

		Marsha.RernLeitner@ihs.gov
	Oglala Sioux Tribe Research Review Board CeCe Big Crow OSTRRB Coordinator	Lisa Dillon Health Administrator P.O. Box 5011 Pine Ridge, South Dakota 57770 (605)867-1704
Phoenix Area IRB	Augusta Hays Phoenix Area IHS IRB Chair Two Renaissance Square 40 North Central Avenue- Suite 600 Phoenix, Arizona 85004 (602)364-5047 Augusta.Hays@ihs.gov	

CDC’s Lead for Tribal Consultation has also been consulted in the development of this project. Her name and contact information are provided below.

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Senior Tribal Liaison for Policy and Evaluation
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A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

The Pine Ridge tribal area has requested \$10 gratuity for participants from their area that are taking part in interviews. This is a usual and culturally expected incentive for interviewees and focus group members and we will extend the \$10 gratuity to other participants. The \$10 incentive is also proposed so that it may increase response rate.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

Staff in the CDC Information Collection Request Office have reviewed this submission and determined that the Privacy Act does not apply because the response data will not be linked with the respondent’s name. Procedures to safeguard the privacy of respondents and anonymous responses are described below.

Information will be collected by a data collection contractor, Missouri Breaks Indian Research, Inc. (MBIRI), a Native American-owned and staffed small business. MBIRI representatives will collect the names and contact information for respondents in order to schedule telephone

interviews and make travel arrangements for those participating in focus groups, however, names will only be maintained temporarily for scheduling purposes and will not be linkable to response data. MBIRI will assign a unique code, the Respondent Identification Number (RIN), to each respondent. The RIN will be assigned to the respondent following the signed consent and the interview, and it will be used to track, store, and analyze the qualitative responses. The information that links the RIN to respondent identifiers will be destroyed before response data is entered into the study database. MBIRI researchers will not share the answers with any person not on the research staff. No identifiable information will be transmitted to CDC.

Focus group discussions will be audio-taped and the tapes will be transcribed for summarization and analysis. The audio-tape machine will be turned off during the participant introductions. Respondent names or other identifiers will not be transcribed or associated with comments made during focus group discussions, and audiotapes will be destroyed following their transcription so that it will not be possible to identify comments from individual respondents in any detailed or summary reports.

The research data will be kept in a secure location, and only the researchers will have access to the data. MBIRI maintains three secure Local Area Network (LAN) sites in Kyle, SD, Eagle Butte, SD, and Timber Lake, SD. Each site is inter-networked via Virtual Private Network (VPN) and is protected by a Check Point Firewall. Each computer in the office has Microsoft Office installed for production and Norton Antivirus installed for virus and spyware security. Each site has a file server which hosts domain logon information for all workstations as a security measure for network resources. All project files will be stored on a limited-access project shared drive, and only project staff members that have been authorized will gain access to the data. All computer files will be regularly backed up by the data manager, and back-ups will be stored in a secure location. Analysis files will only contain the RIN. Paper documents will be kept in a locked cabinet at the MBIRI offices. Upon conclusion of data analysis and report preparation, all files containing respondent names or research identification numbers will be destroyed.

The CDC IRB and the IHS National IRB have determined that the proposed project is exempt from human subjects research regulations promulgated in 45 CFR 46 (see **Attachment 4**). Tribal approval varies from tribe to tribe. Each tribe is considered a sovereign nation with separate laws and requirements. Some tribes do not have their own IRB committee. There are tribes that refer all medical research decisions to the IHS IRB, and there are tribes that require both tribal approval and tribal health board approval. The best way to navigate throughout the different tribes is to contact the tribal council about a project. Even if they do not require a specific approval for the project, it is still a good idea to give them the courtesy of letting them know what will be done in their area, even if their local IHS IRB has given their approval. However, because each tribal area is a sovereign nation, and therefore subject to different processes in which tribal approval is sought, we also submitted applications to each area IRB for approval and to the tribal Review Boards, and Tribes, as applicable. Approval letters from the Oglala Sioux Tribe in Pine Ridge, South Dakota, the Aberdeen Area IRB, and the Alaska Area IRB are also included within **Attachment 4**.

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

The information collection involves a limited number of questions that may be viewed as sensitive by a portion of respondents, but are unlikely to be highly sensitive. The majority of questions are opinion or knowledge-based questions; however, the medical provider interview includes a Systems Issues question (#1) that reflects on the provider's medical practices. In addition, the focus groups are segmented according to the respondent's history of MI. There may be a small risk of discomfort due to such questions asked; however, in the consent forms we let participants know they can answer only those questions they choose to answer, and can stop the interview at any time. If they choose not to answer a specific question the interviewer will simply go to the next question. The potentially sensitive questions are necessary to the purposes of the research study. The consent forms are included in **Attachments 5B, 6B, 7B, and 8B**.

The proposed project does not involve the collection of Race and Ethnicity data. Although some emergency medical care providers who provide services for AI/AN populations will themselves be AI/AN, that information would not be relevant for purposes of analysis. All other respondents are known to be of AI/AN origin. Respondents who participate in the focus group discussions and individual telephone interviews will be AI/AN persons who have had an MI or are considered at high risk. They will be identified through contact with emergency medical care providers and cardiologists working within the Indian Health Service, which only provides services to AI/AN persons. Respondents in the AI/AN community leader group will also be nominated on the basis of their roles in AI/AN communities. This approach is allowable under the exemption for focus on one minority population per HHS policy (<http://aspe.hhs.gov/datacncl/inclusn.htm>).

A.12. ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

A.12.a Burden Hours

Information will be collected through telephone interviews with key tribal community leaders (**Attachment 7A**), individual tribal community members (see **Attachment 8A**), and medical care providers (**Attachment 9A**). Information will also be collected during focus groups involving individual community members who will be separated according to those who have experienced an MI (**Attachment 5A**), and those who have not experienced an MI but are considered high-risk (see **Attachment 6A**). Respondents who are interested in participating in the study will complete an Interest Form (see **Attachment 10**) and return it to the data collection contractor. It is anticipated that a 50% response rate from individuals from three distinct regions, will more than meet the minimum standards for subjects needed for the identification of key perceptions. From the responding key informant interviews, two focus group discussions comprised of 8-12 individuals from across three regions will be conducted.

Burden hour estimates are based on the contractor's previous experience conducting interviews and focus groups with AI/AN populations. The estimate of 5 hours per focus group discussion is culturally tied to traditional practices and is necessary to provide time for participants to discuss the topic and advise on final messages. Culturally, it is important to give all participants a chance to speak and give their opinions, because a hurried interview process can be viewed as

disrespectful in the American Indian culture. To provide respondents with as much time as they need, the burden estimate therefore reflects the time commitment for a substantial portion of the retreat format. The agendas for the focus groups are included (see **Attachments 5B** and **6B**). The focus group discussion for each group will be distributed over a morning session and an afternoon session.

The total estimated burden hours for interviews and two focus groups are 233, as indicated in **Table A.12-1**. Of the 233 hours, an estimated 151 hours are attributed to recruiting and conducting interviews and 82 hours are for recruiting and conducting focus groups.

Table A.12-1. Estimated Annualized Burden Hours

Respondent Type	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden (in hours)	Total Burden (in hours)
Medical Providers	Interest Form	54	1	3/60	3
	Interview Guide for Providers	27	1	1	27
Tribal Community Leaders	Interest Form	30	1	3/60	2
	Interview Guide for Community Leaders	15	1	45/60	11
Individual Tribal Community Members	Interest Form	252	1	3/60	13
	Interview Guide for Individuals	126	1	45/60	95
AI/AN Community Members with Prior MI	Interest Form	12	1	3/60	1
	Discussion Guide for MI Group	8	1	5	40
AI/AN Community Members without Prior MI	Interest Form	12	1	3/60	1
	Discussion Guide for non-MI Group	8	1	5	40
GRAND TOTAL					233

A.12.b Cost to Respondents The estimated cost burden for the interviews and focus groups is \$3,254 as shown in **Table A.12-2**. Wage estimates for tribal community leaders are based on U.S. average hourly earnings from the U.S. Department of Labor, Bureau of Labor Statistics. The hourly wage for medical providers is an average of the various types of providers to be interviewed. Wages for individual community members are also based on estimates. We accessed information for three states (Arizona, South Dakota, and Alaska - the three areas we propose to work in), and used the household size and household income of the three areas to calculate average wage rates. This information was obtained from <http://quickfacts.census.gov/qfd/states/46/46071.html> . Next, we took into account the unemployment rate in each county that we will be working in. For example, in the Dakota area, Pine Ridge reservation in Jackson county, has an unemployment rate of 7%. <http://data.bls.gov/map/servlet/map.servlet.MapToolServlet?state=46&datatype=unemployment&year=2008&period=M03&survey=la&map=county&seasonal=u> . The average wage rate of \$6.00 per hour includes an adjustment for the unemployment rate.

Table A.12-2. Estimated Annualized Cost to Respondents

Respondent Type	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden (in hours)	Average Hourly Wage Rate	Total Cost
Medical Providers	Interest Form	54	1	3/60	\$65.00	\$176
	Interview Guide for Providers	27	1	1	\$65.00	\$1,755
Community Leaders	Interest Form	30	1	3/60	\$15.00	\$23
	Interview Guide for Comm. Ldrs.	15	1	45/60	\$15.00	\$169
Individual Community Members	Interest Form	252	1	3/60	\$6.00	\$76
	Interview Guide for Individuals	126	1	45/60	\$6.00	\$567
Focus Group	Interest Form	12	1	3/60	\$6.00	\$4
	Discussion Guide for MI Group	8	1	5	\$6.00	\$240
Focus Group	Interest	12	1	3/60	\$6.00	\$4
	Discussion Guide for non-	8	1	5	\$6.00	\$240

	MI Group					
	GRAND TOTAL					\$3,254

A.13 ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND RECORDKEEPERS

There are no costs to the participants either (a) total capital and start-up costs, nor (b) operation, maintenance, or maintenance and purchase of services cost to respondents.

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The proposed information collection involves the cost of Federal employee time and costs associated with a contract for data collection and analysis.

The annualized cost of the contract with Missouri Breaks Indian Research, Inc. (MBIRI), is \$100,000, for the one-year period of information collection. The total contract cost over the two-year project period is \$200,000. The tasks to be supported by MBIRI include providing all labor, equipment, materials, supplies, and travel. Labor includes all data collection and analysis, development of key, culturally relevant messages that are consistent with national “Act in Time” campaign messages, identification of culturally relevant methods and styles of delivery for the messages, and to facilitate the contributions of the advisory workgroup, along with the CDC technical monitor. The contractor will pay for flights, housing for one night and meals for focus group members that need to travel, so that there will be no direct costs to respondents. This is necessary to assure participation in the focus groups. The contractor will engage the National Indian Health Board and tribal consultants with regard to the acceptability of the project products.

The cost of Federal government personnel is estimated to be \$8,900 which includes one Federal employee at GS-13 who is the project technical monitor and who will be involved for approximately 10% of her time to coordinate the planning and monitoring of the project.

Table A.14-1 provides a summary of annualized costs for project support provided by Federal personnel and the data collection contractor.

Table A.14-1. Estimated Cost to the Federal Government

Type of Cost	Total Cost
Federal Personnel	\$8,900
Program Funds to Contractor	
• Equipment	\$4,500
• Travel	\$17,500
• Supplies	\$5,000

• Personnel	\$73,000
Total	\$108,900

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is new, one-time data collection.

A.16. PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

A.16.a Tabulation and Analysis Plan

The approach to the analysis of qualitative data flows directly from the research questions and domains (e.g., symptoms identified, acceptability of MI services, accessibility of MI services, etc.) developed in consultation with the CDC, and the MBIRI statistician. The research questions and domains will serve to direct the analysis, but care will be taken to examine emerging ideas and concepts that flow from the qualitative (descriptive) information. The interviews and focus group data will be coded by keywords and conceptual themes and then the codes will be counted to indicate which ones were repeated most often. Frequency counts will be reported for these coded themes. All descriptive interview and focus group data will be analyzed using NVivo, which will identify and post comments into meaningful distinct categories. In addition, pertinent quotations from the interviews will be compiled to illustrate the themes that emerge. Very direct questioning patterns include questions like, “What do you believe will happen as a result of delaying treatment for a heart attack?” A few questions that have a yes/no component (and serve as beginning probes) will be analyzed in a straightforward manner. For example, one question asks, “Do men and women have the same signs and/or symptoms of a heart attack? The summary of the answers will be ‘X’ percent indicated ‘Yes’ and ‘Y’ percent listed ‘No.’

An analytical coding structure will be formulated that reflects the objectives of the study. This coding structure will be flexible so that additional sub-coding of similar or related ideas can be examined and added as analysis progresses. Coding and analysis will continue iteratively. As new themes and issues emerge, all the relevant information will be retrieved and examined for further coding designations. An example of the first approximation of the coding structure is displayed in **Table A.16-1.**

Table A.16-1. Coding Structure – First Approximation of the Coding Structure

What are the Common Themes from the responses?	Do these Themes Vary by Groups? Anticipated areas to be assessed are	What stories emerge for the Responses?	Is there a relationship between past experience and themes	Are the themes or patterns of responses similar to
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Some anticipated themes are listed below.	listed below.	We are looking for examples that tell the story.	discussed?	other studies?
<ul style="list-style-type: none"> *Barriers to obtaining health care *Perceived quality of health care *Main symptoms of heart attack *Response time for emergency services *Where services are that can be accessed for heart attack *Role of traditional medicine 	<ul style="list-style-type: none"> Variation by age Variation by ethnicity Variation by gender Variation by geographic area Variation by acculturation Other variations 	What are the personal stories?	What themes bring out the most emotional responses?	How do the perceptions of these groups match with other studies?

Additionally, some of information from the individual interview form is quantifiable and amenable to traditional data analysis procedures (e.g., means, percents) allowing information to be summarized in tables, charts and graphs. Depending upon the response rates and quality of the information from various regions surveyed, comparisons (i.e., symptoms identification and knowledge, time factors, etc.) by grouping factors (e.g., region, gender, age, etc.) will be possible, illuminating areas of focus for social marketing activities. An example of a display of such information is displayed in **Tables A16-2.1, A.16-2.2, and A.16-2.3.**

Table A.16-2.1. Tables That Summarize the Data to be Collected
Demographic Characteristics of Persons in Focus and Key Informant Groups

Group	Age (average, range)	Ethnicity (% by category)	Income Levels	Gender	Education Levels
A1	38.6 yrs, 17-64	AI/AN Caucasian Other	10-20k 20-35k 35-55k 55-80k Over 80k	Female Male	< H.S. H.S. > H.S. B.S. M.S.+ 6%

A2					
A3					
A4....etc.					
Total All Groups					

Table A.16-2.2. Tables That Summarize the Data to be Collected

Basic Assessment of Themes/Concepts, by Group

Major Themes or Concepts Assessed	Results of Analysis Differences by Demographic Factors	Recommendations	Future Action
Theme 1			

Table A.16-2.3. Tables That Summarize the Data to be Collected

Overall Results (all Groups)

Major Themes or Concepts Assessed	Results of Analysis Differences by Demographic Factors	Recommendations	Future Action

The project time schedule is displayed in **Table 16.3.**

Table A.16-3. Project Time Schedule Table

Activity	Time Schedule
Calls to the IHS Chief Medical Officer (Alaska and Great Plains regions) and the Senior IHS Cardiologist (Southwest region) to initiate the recruitment plan	Immediately after OMB approval
Data collection: key interviews	2-3 months after OMB approval
Data collections: focus groups	4 months after OMB approval
Complete data analysis for key informant interviews and focus groups	2-5 months after OMB approval
Draft report on Focus Groups and interviews and recommendations	6 months after OMB approval
Share findings and draft messages with stakeholders (tribes and advisory workgroup) and obtain	8 months

feedback	
Develop and produce message copy and templates	12 months after OMB approval

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The expiration date for OMB approval of the information collection will be displayed on data collection instruments.

A.18 EXCEPTION TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

There are no exceptions to the certification.

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