

## RECRUITMENT OF AMERICAN INDIANS IN EPIDEMIOLOGIC RESEARCH: THE STRONG HEART STUDY

Martha L. Stoddart, M.S., Betty Jarvis, R.N., Beverly Blake, R.N., F.N.P., Richard R. Fabsitz, M.A., Barbara V. Howard, Ph.D., Elisa T. Lee., Ph.D., and Thomas K. Welty, M.D.

*Abstract: This paper describes the methods used to recruit American Indian (AI) populations for the Strong Heart Study (SHS), a community-based study of cardiovascular disease (CVD) and its risk factors in AI men and women. Recruitment strategies included personal contact by recruiters and drivers/recruiters in remote areas, SHS staff participation in community activities, and mass media. A total of 4,549 participants aged 45-74 years were recruited from 13 American Indian tribes and communities. Overall participation rates were 72%, 55%, and 62%, respectively, for the three study centers (Arizona, the Dakotas, and Oklahoma). Participant feedback and educational material related to risk factor reduction and promoting a healthy lifestyle were emphasized. Participants were likely to be female, young, and nonsmokers. Barriers to recruitment included lack of telephones in a large proportion of households, conflicting beliefs about health/health care/research, fears, taboos, and occasional rumors about study examination procedures. Participants were referred for follow-up of health problems detected by the study. The strong commitment of the participating communities helped to insure the success of the SHS, which can be considered a model for recruitment in future American Indian population-based studies. Success was facilitated by the use of a variety of recruitment techniques.*

Although inclusion of minorities in clinical and epidemiologic research is necessary for valid inferences about health and disease in all segments of the population, minorities are frequently under-represented

in research due to difficulties in recruitment and retention, leading to insufficient data for meaningful analysis in these subpopulations. The National Institutes of Health (NIH) requires that “clinical trials be designed and carried out in a manner to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently from other subjects in the trial” (NIH Revitalization Act, 1993). In addition, NIH policy encourages inclusion of minorities in epidemiologic research (Freedman, Simon, Foulkes, et al., 1995; Swanson & Ward, 1995).

In population-based studies, recruitment of participants can be one of the most challenging tasks. Recruitment goals depend on the makeup of the population of interest and the nature of the study (Johnson & Arfken, 1992). Researchers involved in studies of American Indian (AI) populations face the possibility of unique challenges in addition to the recruitment barriers that typically exist in other minority or general population-based studies. Most AI people take great pride in preserving their rich cultural heritage, some of which by its very nature cannot always be well understood by the general population or even by different AI groups. These cultural differences, which deserve great respect, influence their beliefs about their own health, health care, and research, in general. The same tribal elders who may take a somewhat fatalistic view of their own lives still may have a strong desire to contribute to the understanding of risk factors and diseases that may reduce the quality of or cut short the lives of future generations. Documented historical events may also affect the development of a spirit of cooperation in government-funded studies of the AI people. Added to these cultural differences, many times AI populations are more widely dispersed across rural areas, having no street addresses and no telephones, or, in the case of the younger community members, may be more mobile and thus more difficult to track than other minority or general populations.

The Strong Heart Study (SHS) is the first large, multicenter, population-based study of cardiovascular disease (CVD) and its risk factors in three geographically as well as somewhat culturally diverse AI populations. The study was undertaken because CVD has become the leading cause of death in AI people (U.S. Department of Health and Human Services, 1984) and because CVD mortality rates appear to vary among the various AI communities (Lee et al., 1990; Welty & Coulehan, 1993). The SHS uses standardized methodology to estimate CVD mortality and morbidity rates and to compare CVD risk factor levels among AI groups living in the three different geographic areas of the United States described below. In Phase I of the SHS, participants were invited to come to the local study site for an examination that included written informed consent, a personal interview, a physical examination, and the collection of blood for laboratory tests to estimate the prevalence of CVD and its potential risk factors. Details of the design, methods, and results of the study were published

previously (Howard et al., 1995; Lee et al., 1990; Lee et al., 1995; Welty et al., 1995).

Tribes and geographic areas included in the SHS are the Pima/Maricopa/Papago Indians of central Arizona (Gila River, Salt River, and Ak-Chin Indian communities), seven tribes in southwestern Oklahoma (Apache, Caddo, Comanche, Delaware, Fort Sill Apache, Kiowa, and Wichita), the Oglala Sioux Tribe (Pine Ridge) and the Cheyenne River Sioux Tribe (Eagle Butte) of South Dakota, and the Spirit Lake Tribe (Fort Totten) of North Dakota. These three field centers (Arizona, Oklahoma, and the Dakotas) represent, respectively, the expected low-, intermediate-, and high-risk areas for CVD. They also represent areas of wide variation in climate and living conditions. Many of the AI people live on reservations in Arizona (AZ) and the Dakotas (SD/ND), but there are no reservations in Oklahoma (OK). Due to these differences among centers, the three field centers developed somewhat different recruitment techniques.

Because the study of CVD is the main focus of the SHS and because of budget and time constraints, it was not feasible to collect the extensive data needed for a comparative study of the recruitment methods presented herein. To single out any one technique as best or worst would be difficult, because so many different techniques were used to encourage participation in the study. It is highly likely that each method appealed to different segments of the study population. It is also likely participants exposed to a combination of some or all of the recruitment techniques might not be able to pinpoint which one method was most influential in their decisions to participate.

The main objective of this paper is to describe the preliminary work conducted before Phase I examinations began and the wide range of recruitment techniques and strategies that were employed during Phase I of the study (June 1989-January 1992). This paper also presents a comparison of participants with a sample of nonparticipants, to examine the possibility of a biased sample due to the recruitment methods used in the SHS. The success of this combination of techniques is evidenced by the achievement of greater than 50% recruitment rates and reaching the goal of examining at least 4,500 participants over the 30-month examination period. During this time, genuine feelings of mutual respect and trust between SHS staff and the participating AI groups grew and, in the end, remained.

## Methods

### Prerecruitment Activities

The SHS was funded by the National Heart, Lung, and Blood Institute (NHLBI) as a cooperative agreement. Under this funding mechanism, NHLBI staff participated as collaborators in the conduct of the study. This role offered an opportunity for early coordination that is not available under most other study organizational structures.

### Preaward Activities

In the initial Request for Applications, guidelines and requirements that were designed to enhance recruitment success were incorporated into the solicitation. Early discussions were held with representatives of the AI communities and the national AI organizations. This dialogue identified language and procedures associated with the study design that might be viewed as inappropriate by AI people as well as areas of potential misunderstanding within the AI community. The NHLBI Ad Hoc Committee on Minority Populations helped with this early planning. The committee includes AI as well as other minority groups to advise the NHLBI on minority issues. This group was helpful in supporting the study concept, as well as in formulating the plan for the study.

Early and continuing collaboration with the Indian Health Service (IHS) served to inform the agency of plans and to obtain IHS input on the possible impact of the proposed study upon existing programs, resources, and facilities, and to minimize the potential for interagency conflicts as the study progressed. The SHS found the IHS receptive to this early communication, and this resulted in their assistance in identifying existing resources that might be useful during the planning phase of the study. As an example, the IHS database was used to generate statistics on the health problems of specific IHS areas and service units. The regional IHS offices were also helpful in providing access to local IHS facilities and resources at each of the three study centers. Access included accommodations for reviewing medical records of participants (with written permission from participants) and sharing IHS hospital/clinic space, equipment, and occasionally their personnel.

Finally, steps were built into the NHLBI solicitation process to ensure that the Principal Investigators (PIs) and their proposed study communities would be comfortable with each other, have a commitment to the interests of the other study centers, and have respect for the concerns of the specific AI communities. This was addressed by two approaches. First, evaluation of proposals included evidence of previous acceptable participation rates and experience of staff members in working with the AI communities.

This was generally assessed by the inclusion of resolutions of support approved by the tribal governments as well as letters of support from key individuals from the involved communities. It was clearly helpful that the SHS PIs had long-standing relationships with the AI communities prior to the solicitation. Second, prior to the awards, NHLBI staff made site visits to each potential center to evaluate the spirit of cooperation that existed among the study personnel and key individuals from the communities. It was clear that chances of success would be enhanced by a strong commitment of the leadership, members of the AI communities, and the PIs and study staff members to each other and to the study.

### **Preexamination Activities**

After funds were awarded, a second series of activities was essential for successful recruitment efforts. Foremost among these was a concerted effort to obtain community involvement in the planning of the study. SHS PIs and staff held open community meetings, as well as meetings with tribal leaders, as the protocol was being developed to describe plans and to obtain feedback from the communities. The input of community members was vital in the design of the study questionnaires. Tribal representatives collaborated with the scientists in writing sensitive and appropriate questions suitable for their communities. Special consideration was given to questions regarding income and alcohol use. For example, rather than asking participants for a dollar amount of annual household income, it was decided that it would be less offensive to ask if they received enough income to pay their bills. Further, it was the opinion of some of the representatives that, because of their culture, tribal members might not understand or might be offended by some of the phraseology and/or terminology used in standardized questionnaires designed to measure psychosocial variables such as depression, stress, and social support in the general population. For example, simple terminology such as the word "stress" and the phrases "feeling on top of things" and "feeling blue" did not translate well among some Native-speaking tribal elders. Another area where the assistance of tribal representatives was particularly valuable was in writing questions to measure American Indian traditionality. What constitutes being traditional varies by tribe/community. One might assume that tribal members who frequently attend powwows must be more traditional; however, not all tribes and communities hold powwows. Furthermore, some tribes and communities that do hold powwows do not consider them as being traditional. Additionally, the tribal representatives suggested areas of interest that would be useful for health care planning in their communities. As more and more tribes become less dependent on the Indian Health Service for their health care planning, results of studies such as the Strong Heart Study can provide them with information to assist them in allocating their health monies. Tribal clinic administrators were interested in developing clinic education programs designed for disease

risk factor reduction to prevent future disease among tribal members and in information that would assist in short- and long-term planning related to patient care for health problems already existing. The protocol was pilot tested in the communities, so that modifications could be made to any troublesome areas before the examinations began.

In addition to involving the communities in the study protocol development, much time and attention were devoted to producing a poster and logos to promote the study. The SHS hired local AI artists to design a poster and logo that would be appealing and acceptable to all 13 of the participating tribes. An OK AI artist designed the SHS logo (see Figure 1). At the center of the logo is the traditional valentine heart, which is more universally recognized than the anatomically correct heart, with the state maps of the three participating areas superimposed on top of the heart in an arrangement similar to their respective positions on a United States map. Immediately surrounding the heart and maps are the names of the 13 participating tribes and communities, listed in alphabetical order in a circle, without preference to any single tribe or community. The design is completed with the name of the study, "Strong Heart Study," in another circle, outside the circle of tribal names. Representatives of the participating tribes suggested this name, because the study is about cardiovascular disease and all tribes could relate to the desire for maintaining a strong heart. The circle is a meaningful symbol in several areas in the lives of AI people. For example, it represents the shape of the earth and the sun; many ceremonies at powwows are held in circles; early AI calendars were round; it symbolizes the cycle of life, everything begins and everything comes back; it suggests no end.

A Lakota college student did the artwork for the poster. It is a traditional medicine wheel, again circular, divided into four different-colored sections, which represent the four seasons and the four directions. Superimposed on the wheel are the American bald eagle and a buffalo skull on either side of a traditionally dressed AI man holding a ceremonial pipe. The American bald eagle played a major part in the story of creation for some AIs, and the buffalo is a sacred animal that was the main source of food, clothing, and shelter for early AI people. Four eagle feathers hang from the bottom of the medicine wheel. At the bottom of the poster is the wording, "The Strong Heart Study—A study of cardiovascular disease in American Indians supported by the National Heart, Lung, and Blood Institute and the Indian Health Service." Tribal representatives approved the logo and poster designs as having symbolism that would be accepted and respected by and hold some meaning for all 13 of the participating tribes and communities.

A brochure was developed to explain the purpose of the study, the tests and procedures included in the study, why the study would be beneficial to the participants and to the communities, and a point of contact (individualized by center) for further information or to schedule an

Figure 1  
Strong Heart Study Logo



appointment. The brochure also included a letter from Everett Rhoades, M.D., then Director of the IHS, encouraging tribal members to participate for their own benefit as well as for the benefit of the communities. This brochure was given to all potential participants, as well as to all participating tribes, tribal leaders, and recruiters, to publicize the study.

**Recruitment Activities**

Because the SHS is the first large-scale, multi-center, minority population study of its kind, there was limited published information available about successful recruiting methods for such a study, much less for a study in such a geographically and somewhat culturally diverse AI population as in the SHS. This diversity dictated that each of the three

SHS examination centers be flexible and make changes and adjustments when necessary to develop an overall recruitment package that worked well in their particular situation. However, all three centers used some combination of the same basic methods discussed below.

### **Identification of Eligible Population**

All members of the 13 participating tribes aged 45-74 years who resided in their communities were eligible for participation. Most of the prospective participants were identified by name and their eligibility was determined through information contained in tribal rolls supplied by the local Bureau of Indian Affairs and tribal offices. Other methods for finding eligible prospective participants included advertising the study through the media, attending community gatherings such as powwows, local health fairs, and periodic community meetings.

### **Personal Contact**

Early in the study, both the AZ and the SD/ND centers hired local recruiters/drivers. They made home visits to invite eligible people to the examination and to provide transportation to the clinic when necessary. If potential participants were not at home, SHS information was left for them on a door hanger printed with "SORRY I MISSED YOU." In OK, SHS staff, particularly Tribal Liaisons, contacted eligible people, either by telephone or in person; and a full-time recruiter was not required until over a year after examinations began.

Every effort was made to enlist recruiters from each participating tribe or community included in the study. In remote areas where there were no street addresses and no telephones, the centers selected recruiters with a thorough knowledge of community geography and personal acquaintance with the prospective participants. The study also enlisted community members who were active in community and tribal activities (e.g., powwows and lunch programs for the elders) to help with recruitment. In some of the communities, bilingual recruiters were helpful.

In addition to the full-time SHS recruiters, many community members volunteered to help with recruitment without compensation. For example, Tribal Administration staff, Community Health Representatives (CHRs), Senior Center staff, clinic staff, and community health nurses, as well as participants who had completed their examinations, also helped to promote the study among eligible community members. The CHRs were particularly helpful by informing the PIs of potential problems in the community that might affect the SHS.

Recruiters were well informed concerning the eligibility criteria and had a thorough knowledge of the study protocol, in order to give accurate answers to questions that arose from prospective participants. When the recruiter did not have previous experience with medical studies, a study nurse or other staff member with a medical background and/or a thorough

knowledge of the study protocol accompanied the recruiter. After initial recruitment efforts, it was especially helpful when the recruiters had participated in the study and could then provide first-hand information regarding the examination.

Recruiters were flexible with their time, frequently making multiple weekday and/or weekend and holiday contacts, thus maximizing their chances for finding prospective participants.

### **Mass Mailings**

As additional potential participants were identified and home address databases were developed, mass mailings of invitation letters were utilized. Mailings were initiated early in the study in SD/ND, where potential participants lived as much as a ten-hour drive away from the central research office, and in OK, a more urbanized area without reservations. In the last year of the examinations, the AZ center sent a letter to all remaining eligible people, mainly those with known addresses who lived off the reservation.

In OK, initial mailings were targeted at the people who were currently eligible but would become ineligible because of age before the end of the examination period. Included with the letter of invitation were the four-page brochure (described above), a postage-paid card to be returned to the study offices, and/or toll-free telephone numbers to be called if the prospective participant was interested in participating in the study. During the ongoing process of building and updating the databases, about 1500, 2500, and 4000 invitations, respectively, were mailed by the AZ, OK, and SD/ND study centers.

### **Media Recruitment**

Local radio broadcasting and print media were also used to promote the SHS. Radio spots were either purchased or were broadcast as public service announcements by local radio stations, for SHS advertisements. During some AI radio programs, interviews with the PIs about the SHS, some in the native languages, were broadcast in the study areas. Articles that described the SHS and solicited participation were published in tribal newsletters and area newspapers.

### **Community Visibility and Involvement**

The three SHS centers co-hosted benefit powwows to help raise funds for local health-related programs and set up booths at community health fairs and other community activities. These gatherings were all well attended by prospective participants and offered free health education material and health checks such as blood pressure readings and random glucose testing, drawings for small prizes, and souvenirs that promoted the study. For example, water bottles stamped with the SHS logo and cardboard fans printed with "I'M A STRONG HEART STUDY FAN" were

particularly welcomed in the August heat of OK at the annual American Indian Exposition.

At all three study centers, input and formal approval from each participating tribe were obtained at all stages of the study. Tribal members were invited to periodic community meetings, where PIs delivered presentations on the progress and results of the study, heard feedback from community members, and answered questions from attendees. Additional community meetings were held when PIs from other centers were visiting, either for the quality control visits or for Steering Committee meetings, which were rotated among the field centers. These meetings also provided the opportunity for SHS staff to schedule appointments for the examinations.

As mentioned above, part of the intensive efforts to promote participation of the AI communities in the study was to hire qualified community members for staff positions. In Phase I of the SHS, 66 persons were employed, 38 of whom were AI. In addition, a program for AI students was begun to provide experience in research and to expose young people to career opportunities in medicine and research. This approach reflected the desire of the PIs to increase the number of trained AI investigators available to conduct future studies and to improve health care. The SHS utilized a total of 78 health professions students (38 AI) to help with the study during Phase I.

## **Examination Activities**

### **Compensation and Promotional Materials**

The SHS gave participants a small amount of money to compensate them for their time and travel and gave them T-shirts and other useful items (water bottles, mugs, and tote bags), all printed with the SHS logo, to show the appreciation of the staff. These promotional items were well received by participants and also served to increase the visibility of the study within the community. Because the study protocol required participants to be fasting when they came in for the examination, a healthy morning snack or a small lunch was provided after the blood samples had been drawn.

For the convenience of participants who could not participate in the study on a weekday, all three SHS centers scheduled weekend examinations. One center was able to obtain some data for parts of the examination that did not require fasting status during evening examinations, while still observing protocol timing requirements for collecting all data on an individual participant.

### **Examination Results and Follow Up**

The study protocol emphasized patient involvement and education, beginning with the informed consent process before the examination began. The participants read the consent form or it was read to them, if necessary. The participant was fully informed about all aspects of the examination and encouraged to ask questions. After the participant gave his/her approval by signing the consent form, the examination began. The participant received a copy of the informed consent, educational brochures regarding a healthy heart lifestyle, and information about the importance of risk factor reduction and lifestyle changes to decrease his/her risk for cardiovascular and other chronic diseases. The SD/ND center gave each participant a personalized, AI-specific health risk appraisal that provided specific advice on how to improve his/her health through risk factor modification (Welty, 1988; Welty, 1989). The SD/ND center also offered cancer screening for breast, cervical, and colorectal cancer through support provided by the National Cancer Institute (Welty, Zepher, Schweigman, Blake, & Leonardson, 1993).

Referrals and follow-up for adverse health findings were also emphasized throughout the SHS examination period. The study protocol outlined specific guidelines to be followed by SHS personnel for emergency referral for any life-threatening illness and immediate, urgent, and routine referral for non-life-threatening adverse findings. A summary of the examination, along with an explanation of test results and suggestions for follow-up, was mailed to each participant. The summary and any other diagnostic information obtained through the SHS were also sent to personal physicians and/or medical facility, upon request of the participant. In addition, a SHS newsletter describing progress of the study and preliminary results was composed, printed, and sent out to all participants, tribal leaders, and health care providers twice a year.

### **Comparison of Eligible Participants and Nonparticipants**

Due to the large sample sizes sought in the SHS (1,500 participants per center in the eligible age range), it was clear from the outset that our samples *de facto* would be representative of the underlying populations. However, the possibility remained that nonparticipants might differ substantially from our sample groups due to any number of reasons. To assess whether nonparticipants deviated in any major way, each field center generated lists of at least 100 eligible nonparticipants using a random number selection process. A nonparticipant interview form was administered to these people by trained interviewers to gather information about their medical histories and some major CVD risk factors. Because all information obtained from nonparticipants was self-reported, only information from the participant medical history, which was administered by the examiner and did not include any test results, was used for comparison purposes. The exceptions were height and weight, which were self-reported in nonparticipants and measured in participants.

## Results

The goal of obtaining at least 1,500 eligible participants per geographic area was met at all three SHS centers; AZ examined 1,545, OK examined 1,549, and SD/ND examined 1,557. Later, during the data cleanup stage, 102 persons were found to be ineligible because of their age, tribe, or having been examined twice (duplicate examinations were discarded), which left AZ with 1,500, OK with 1,527, and SD/ND with 1,522 eligible participants for data analysis.

Participation rates were calculated for all three centers. The numerator was the number of eligible participants examined between June 1, 1989 and January 31, 1992. The denominator included all eligible people in the SHS communities during this period of time. People who were eligible for the study but died before the examination period ended were included in the denominator. However, those who could not be located and those who moved out of the study area during the Phase 1 examination period were excluded. Existing tribal rolls required extensive cleanup before denominators could be determined. In all three centers, enrollment rates were above 50%, were higher for females than for males, and were highest in the youngest age group (Table 1). Availability of telephones in the households of participants varied by center, with 43%, 72%, and 52%, for AZ, OK and SD/ND, respectively.

Table 1  
Participation Rates (percent) by Age, Center, and Gender

Age Group	AZ				OK				SD/ND			
	M		F		M		F		M		F	
	%	N	%	N	%	N	%	N	%	N	%	N
<b>45-54</b>	77.7	(314)	90.6	(481)	61.3	(309)	64.9	(360)	52.2	(325)	61.0	(413)
<b>55-64</b>	62.8	(159)	76.8	(315)	56.7	(203)	68.4	(333)	52.7	(225)	60.5	(288)
<b>65-74</b>	38.4	(73)	52.2	(158)	53.5	(131)	57.0	(191)	43.5	(108)	53.8	(163)
<b>All</b>	64.5	(546)	76.8	(954)	58.1	(643)	64.2	(884)	50.7	(658)	59.3	(864)
<b>All</b>	71.8(1500)				61.5(1527)				55.3(1522)			

A comparison by center of participants and nonparticipants on selected variables is shown in Table 2. Participants were slightly younger than nonparticipants; however, the difference was significant only for females in OK ( $p < 0.001$ ). One major difference between participants and nonparticipants was the gender distribution ( $p < 0.0001$ ), reflecting the higher participation rate among women. After adjustment for age, the gender-specific rates of self-reported diabetes were similar for both participants and nonparticipants in all three study centers. There were significant differences between participants and nonparticipants with respect to self-reported hypertension for both genders in AZ and for females in SD/ND; the gender-specific rates for hypertension in OK were not significantly different. Participants were likely to be nonsmokers in all three centers; however, the only significant difference from nonparticipants was among SD/ND males (less among participants). The significant differences in body mass index (BMI), which is a widely used indicator of obesity and is defined as weight in kilograms divided by height in meters squared, for females in AZ and for both genders in SD/ND were the result of the tendency of nonparticipants to report themselves to be lighter and taller than participants. Significant differences were found for both height (shorter participants) and weight (heavier participants) among AZ females but only for height (shorter participants) among males in AZ, and for weight (heavier participants) among males in SD/ND.

### Discussion

Without the experience of any previous studies similar to the SHS and a lack of publications about unsuccessful ones, the SHS charted its own course with careful planning and community involvement during the prerecruitment activities. Publicity that resulted from community involvement in the prerecruitment activities (described above) helped to fill the examination slots at the beginning of the study. Some participants examined during the early stages of the study were eligible local community leaders and/or friends and relatives of the SHS staff. Several of the staff were recruited from the participating communities. As more people were examined and voiced positive comments about the study to others, interest among other eligible people increased. However, it quickly became obvious that, in order to reach recruitment goals, the SHS could not afford to rely on any single recruitment method but would have to incorporate a combination of methods and techniques to reach all segments of such a diverse group of potential participants.

Throughout Phase I of the study, the SHS staff closely monitored participation levels by comparing observed levels of participation with the levels needed over a certain time period, e.g., weekly or monthly, in order to meet the goal of at least 1,500 participants at each of the three field centers over the time period for which Phase I was funded. Whenever

Table 2  
Comparison of Participants and Nonparticipants

	AZ		OK		SD/ND		TOTAL	
	Part.	Nonpart.	Part.	Nonpart.	Part.	Nonpart.	Part.	Nonpart.
<b>N</b>	1500	100	1527	100	1522	111	4549	311
<b>GENDER (%)</b>								
Female	64 <sup>1</sup>	38	58	57	57 <sup>1</sup>	42	59 <sup>1</sup>	46
<b>MEAN AGE (yr)</b>								
Female	56	57	57 <sup>1</sup>	61	57	57	57 <sup>1</sup>	59
Male	55	57	56	59	56	57	56 <sup>1</sup>	58
<b>CURRENT SMOKER (%)</b>								
Female	13	16	31	20	45	55	29	30
Male	30	34	37	37	53 <sup>2</sup>	69	40 <sup>2</sup>	48
<b>HYPERTENSIVE (%)</b>								
Female	56 <sup>2</sup>	29	38	44	30 <sup>2</sup>	15	42 <sup>2</sup>	30
Male	59 <sup>2</sup>	44	38	26	32	22	42 <sup>2</sup>	31
<b>DIABETIC (%)</b>								
Female	64	61	32	33	33	26	44	38
Male	58	48	29	42	23	27	35	38
<b>MEAN HEIGHT (cm)</b>								
Female	158 <sup>2</sup>	160	160	161	161	163	160 <sup>2</sup>	161
Male	171 <sup>2</sup>	175	174	174	175	176	173 <sup>2</sup>	175
<b>MEAN WEIGHT (kg)</b>								
Female	83 <sup>2</sup>	75	80	78	78	74	80 <sup>2</sup>	76
Male	91	88	92	89	88 <sup>2</sup>	82	90	86
<b>MEAN BMI (kg/m<sup>2</sup>)</b>								
Female	33 <sup>2</sup>	29	31	30	30 <sup>2</sup>	28	32 <sup>2</sup>	29
Male	31	29	30	29	28 <sup>2</sup>	26	30 <sup>2</sup>	28

<sup>1</sup> $p < 0.05$ , comparing participants and nonparticipants

<sup>2</sup> $p < 0.05$ , comparing participants and nonparticipants, adjusting for age

participation levels began to drop, possible reasons were examined, using feedback from participants and potential participants to adjust recruiting strategies or to make adjustments in the examination routine, within the guidelines of the protocol.

The examination required 2 to 4 hours to complete. Work schedules and community activities such as powwows, fairs, funerals, and holiday celebrations made scheduling difficult. Weather conditions, including extreme heat in Arizona, harsh winter weather in South and North Dakota, and rainy seasons also hampered the recruitment effort. These factors

were addressed through repeated participant contacts, rescheduling of appointments, evening and/or weekend clinics, and extending the recruitment period. In all cases, community members worked effectively with the investigators in solving these problems.

When looking at mass mailing as a recruitment method, one should take into consideration the source of mailing addresses and the method of mailing (bulk rate or first class). In the experiences of the SHS in some locations, where mass mailing was used early in the study, the address lists obtained from tribal and Bureau of Indian Affairs records were not up-to-date. Bulk mailing at the lowest cost does not allow return service. Even if first-class mail is used, forwarding orders do not stay in effect long enough to be useful. In areas where people have telephones, many times their numbers are unlisted, thus eliminating the use of recruiting by telephone and of a local telephone directory to obtain current addresses.

Because of these problems with the use of telephone numbers and addresses for recruiting, the SHS relied heavily on personal contact by local community members and recruiters who were better able to locate potential participants. Personal contact worked well for the SHS; however, some recruiters exhausted their contacts within the community before the recruitment quota was met. Additional recruiters with different ties to the community were then utilized.

Potential participants were contacted multiple times by different methods, unless they asked not to be contacted, and were not considered as nonparticipants until the examination phase was complete. Some participants who initially refused to participate changed their minds as the study progressed. Many prospective participants missed multiple appointments before finally completing the examination. In the SD/ND center toward the end of the Phase I examination period, eligible participants who had failed to keep previous appointments were asked to sign a form indicating that they did not wish to participate in the SHS. Often, they would not sign such a form but rather would keep the next appointment that was made for them.

In addition to the impediments encountered in the recruitment effort that resulted from the conflicting beliefs about health/health care/research referred to earlier, some potentially harmful rumors developed. During the early stages of the SHS, a rumor surfaced about the motives of another unrelated and unsuccessful study of a tuberculosis vaccine being tested in one of the study communities. Other types of rumors that had to be addressed were, for example, the possible use of DNA from the blood specimens that were drawn in an attempt to either prove or disprove an individual's degree of Indian blood or if they had committed a crime. Additionally, because of AI culture, there was some concern that the blood specimens would be held in perpetuity, long after a participant had died, not allowing the soul to rest, or that they might be used in an attempt to create new life. Other problems resulted from the usual complaints one

might expect to hear related to pain or bruising that can accompany any blood-drawing procedure but when discussed in the community may be blown out of proportion. These problems were overcome by many means including hiring staff from the community, maintaining an ongoing dialogue with CHRs, tribal leaders, and medical staff, and conducting periodic meetings in the various communities for the Strong Heart Study PIs and staff to talk to tribal members and leaders.

The SHS participants clearly were representative of the underlying communities, since they comprised greater than 50% of the eligible populations in each of the three centers. In addition, it appears that nonparticipants were not markedly different from the participants. Although some statistically significant differences were found between the small random samples of nonparticipants in comparison to the corresponding participant groups, these differences were generally small and sporadic. None of the differences in any of the tested variables held true for all three centers, and only occasionally for both genders within a center.

Perhaps the most notable differences were in weight and self-reported hypertension. Since weight was a measured variable in the participants but a reported variable in the nonparticipants, it is not surprising that self-reported weights were lower in the nonparticipants than carefully documented weights gathered for the participants. With respect to hypertension, it is possible that actual prevalence may be the same in both participants and nonparticipants. It is conceivable that the participants were more conscious of their health status or that nonparticipants were more likely to deny health problems, particularly when their reports would not be verified through actual measurements. In any case, the differences found between participants and nonparticipants, as detailed in Table 2, are small in size, sporadic in nature, and possibly more reflective of the inaccuracies of self-reported data than of real differences. Thus, we are confident in concluding that the SHS cohorts are quite representative of the 13 participating tribes and three geographic areas.

The Strong Heart Study achieved its recruitment goals at each center by working closely with the participating communities at all levels and by demonstrating a clear commitment to benefit the individual, communities, and future generations of the participating American Indian communities. These goals were (or will be) achieved by referring participants with health problems for care, committing to share study results and data, keeping the participants informed of study findings through Strong Heart Study newsletters, and training young people in epidemiologic research. Through these study activities, the communities also became committed to the success of the study. Because of the large number of American Indian employees and students affiliated with the study, American Indian communities will be better able to conduct health research in the future.

Sensitivity to the needs of the communities, respect for cultural differences, and flexibility to meet variable conditions are essential to successful recruiting within the American Indian community. The lessons of the Strong Heart Study experience should be readily applicable to other studies of American Indian populations.

Martha L. Stoddart, M.S.  
Center for American Indian Health Research  
College of Public Health  
University of Oklahoma Health Sciences Center  
P.O. Box 26901, CHB-112  
Oklahoma City, OK 73190  
Phone: (405) 271-3090, X-46721  
Fax: (405) 271-4390  
E-mail: martha-stoddart@ouhsc.edu

#### References

- Freedman, L. S., Simon, R., Foulkes, M. A., Friedman, L., Geller, N. L., & Gordon, D. J. (1995). Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993—the perspective of NIH clinical trialists. *Controlled Clinical Trials, 16*, 277-285.
- Howard, B. V., Lee, E. T., Cowan, L. D., Fabsitz, R. R., Howard, W. J., Oopik, A. J., Robbins, D. C., Savage, P. J., Yeh, J. L., & Welty, T. K. (1995). Coronary heart disease prevalence and its relation to risk factors in American Indians: The Strong Heart Study. *American Journal of Epidemiology, 142*, 254-268.
- Johnson, K. M., & Arfken, C. L. (1992). Individual recruitment strategies in minority-focused research. *Report of the workshop on health behavior research in minority populations: Access, design, and implementation* (NIH Publication No. 92-2965). Washington, DC: U.S. Department of Health and Human Services.
- Lee, E. T., Howard, B. V., Savage, P. J., Cowan, L. D., Fabsitz, R. R., Oopik, A. J., Yeh, J. L., Go, O., Robbins, D. C., & Welty, T. K. (1995). Diabetes mellitus and impaired glucose tolerance in three American Indian populations aged 45-74 years: The Strong Heart Study. *Diabetes Care, 18*, 599-610.
- Lee, E. T., Welty, T. K., Fabsitz, R., Cowan, L. D., Le, N.-A., Oopik, A. J., Cucchiara, A. J., Savage, P. J., & Howard, B. V. (1990). The Strong Heart Study—A study of cardiovascular disease in American Indians: Design and methods. *American Journal of Epidemiology, 132*, 1141-1155.
- NIH Revitalization Act. (1993). Subtitle B, Part I, Sec. 131-133.
- Swanson, G. M., & Ward, A. J. (1995). Recruiting minorities into clinical trials: Toward a participant-friendly system. *Journal of the National Cancer Institute, 87*, 1747-1759.

- U. S. Congress. (1986). *Indian health care* (OTA-H-290). Washington, DC: Office of Technology Assessment.
- U.S. Department of Health and Human Services. (1984). *Indian Health Service chart series book*. Washington, DC.
- Welty, T. K. (1988). Indian-specific health risk appraisal developed. *The IHS Primary Care Provider*, 13, 65.
- Welty, T. K. (1989). Finding the way—Indian-specific HRA released. *The IHS Primary Care Provider*, 14, 64-65.
- Welty, T. K. & Coulehan, J. L. (1993). Cardiovascular disease among American Indians and Alaska Natives. *Diabetes Care*, 16, 277-283.
- Welty, T. K., Lee, E. T., Yeh, J. L., Cowan, L. D., Go, O., Fabsitz, R. R., Le, N. A., Oopik, A. J., Robbins, D. C., & Howard, W. J. (1995). Cardiovascular disease risk factors among American Indians: The Strong Heart Study. *American Journal of Epidemiology*, 142, 269-287.
- Welty, T. K., Zephier, N., Schweigman, K., Blake, B., & Leonardson, G. (1993). Cancer risk factors in three Sioux tribes: Use of the Indian-specific health risk appraisal for data collection and analysis. *Alaska Medicine*, 35, 265-272.

#### Authors' Note

This study was supported by cooperative agreement grants (U01HL41642, U01HL41652, and U01HL41654) from the National Heart, Lung, and Blood Institute.

The authors acknowledge the assistance and cooperation of the Ak-Chin Papago/Pima, Apache, Caddo, Cheyenne River Sioux, Comanche, Delaware, Spirit Lake, Fort Sill Apache, Gila River Pima/Maricopa, Kiowa, Oglala Sioux, Salt River Pima/Maricopa, and Wichita Indian communities. The authors would also like to thank the Indian Health Service hospitals and clinics at each center and to acknowledge the tireless efforts of the Strong Heart Study field staff. The views presented in this paper are those of the authors and do not necessarily reflect those of the Indian Health Service.