Supporting Statement B for

The Atherosclerosis Risk in Communities Study (ARIC)

OMB Number: 0925-0281
January 3, 2011

Dr. Hanyu Ni
6701 Rockledge Drive MSC 7934
Bethesda, MD 20892
Phone: 301-435-0448
Fax: (301)480-1455
E-Mail: nihanyu@mail.nih.gov

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B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

B.1.a. Design Summary

ARIC is both a prospective epidemiologic study and a community surveillance study designed to investigate the etiology and natural history of atherosclerosis and its clinical sequela. The prospective epidemiological component, called the Cohort component, examines and follows a sample of approximately 4,000 men and women in each of four communities. The Community Surveillance component identifies from hospital and death records a sample of all MIs and CHD which occur in all age eligible residents in the community. For events occurring after 2005 the age range for MI and CHD is extended to 84 and hospitalized heart failure information is identified on all community residents over age 55.

B.1.b. Respondent Universe

ARIC is conducted in four geographically distinct communities: Forsyth County, North Carolina; Jackson, Mississippi; Minneapolis suburbs, Minnesota; and Washington County, Maryland. Each community has recruited approximately 4,000 men and women between the ages of 45 and 64 at visit 1 in 1987-89. The cohort in Jackson, Mississippi is sampled and recruited to have an all black population. The population (**Table B.1.b.1**) and social and economic (**Table B.1.b.2**) characteristics of the communities are summarized in the following tables. In the Community Surveillance component, sampling percentages are based on specific diagnostic codes. As described in greater detail in section B.2.b., the study obtains a weighted sample on all fatal and non-fatal cases of MI and CHD in all residents aged 35-84.

ARIC was designed to collect data in four diverse communities. This design was chosen so that data could be obtained for groups that differed by geography, race, and socioeconomic status. Each community provides information on the occurrence and trends in CHD in a unique environmental setting. The cohort samples were drawn from each community so that inferences about association between risk factors and disease can be made from diverse population groups. The diversity of the groups permits evaluation of the consistency of any observed association. Thus, it was important to maximize the diversity rather than attempt to obtain a random sample of the United States. It was also important to select communities in which identification, repeated examinations, and follow-up of a cohort would be possible and linkage between CHD occurring in the community and the cohort could be made. ARIC was not designed to select either a random or representative sample of the entire U.S. population.

Table B.1.b.1. Population Characteristics, 2000

Study Community	Total	Ages 35-84
Forsyth County, North Carolina	306,067	153,330
Jackson, Mississippi	184,256	79,398
Minneapolis suburbs, Minnesota	240,797	120,031

Washington County, Maryland	131,923	69,100
Total	**863,043**	**421,859**

Table B.1.b.2. Social and Economic Characteristics, 2000

Community	% Black	% Urban	% Educ 12+	Median Income ($)
Forsyth County, NC	26	75	82	42,097
Jackson, MS	42	100	79	30,414
Minneapolis suburbs, MN	1	100	85	56,846
Washington County, MD	9.1	57	83	51,034

B.1.c. Cohort Sampling

As described in the original submission to OMB for this study, a probability sample of each community was conducted to select persons eligible for the Cohort component of ARIC. Though the sampling techniques were not the same (list and household samples), each method is designed to yield representative samples of each community. The number of persons in each community and actual Visit 1 clinic attendance is shown in **Table B.1.c.1**.

Table B.1.c.1. Numerical Estimates and Sample Respondents

Study Community	Number in Community Ages 45-64	Number Sampled and Attending Clinic Visit
Forsyth County, North Carolina	50,424	4,035
Jackson, Mississippi (Black)	11,480	3,728
Minneapolis, Minnesota	36,546	4,009
Washington County, Maryland	24,146	4,020
Total	**122,596**	**15,792**

Response rates at each stage of sampling and recruitment for Visit 1 are shown in **Table B.1.c.2**. As can be seen, the response rates vary across the four communities.

Table B.1.c.2. Response Rates to Stages of Recruitment, Visit 1

Recruitment Stages	Forsyth County	Jackson City	Minneapolis Suburbs	Washington County
	Percent Response			
Household Enumeration	97	81	91	82
Home interview	80	81	83	92
Clinic completion	67	46	72	79
Overall recruitment	65	37	66	65
	Total Number of Participants Seen in Each Clinic:			

Participants	4,035	3,728	4,009	4,020
	Total Number of Participants Seen:			**15,792**

The poorer response rate among the black population in Jackson was expected and noted in the original OMB submission. Because there is a serious lack of information on CHD in blacks, the NHLBI regards the inclusion of a black cohort to be essential in ARIC despite the higher non-response. Every effort has been made to minimize these non-response rates (see section B.3.). Early in ARIC, the Jackson community began using a list sample, adopting the methods used in Minneapolis and Washington County. This change, from a household sampling method, permitted effort to be put into recruitment of eligible persons and not on the inefficient listing and enumeration of ineligible households (i.e., white households).

Overall participation at Visit 2 was 93 percent, at Visit 3 was 86 percent and at Visit 4 was 81 percent. Although Jackson has lower response rates for clinic visits, it has a high response rate for the annual follow-up (> 96%). Overall response rates for the annual follow-up telephone call have been very high (> 91%, **Table B.1.c.3**). At contact year 21, the response rate was 91.0%. We anticipate maintaining this level of response for this proposal.

Table B.1.c.3. Response to Annual Follow-up and Clinic Visits through Contact Year 21, by Field Center

	Percent Response				
	Forsyth County	**Jackson City**	**Minneapolis Suburbs**	**Washington County**	**Total**
Contact Year 2	99.5	98.5	99.9	99.8	**99.4**
Contact Year 3	99.2	98.4	99.7	99.7	**99.3**
Contact Year 4	98.8	99.0	99.8	99.7	**99.3**
Contact Year 5	98.7	98.4	99.3	99.1	**98.9**
Contact Year 6	97.8	97.3	98.5	98.8	**98.1**
Contact Year 7	97.4	97.8	98.1	99.0	**98.1**
Contact Year 8	98.0	96.5	96.9	98.5	**97.5**
Contact Year 9	97.5	96.5	96.5	98.2	**97.2**
Contact Year 10	94.2	96.5	96.2	97.5	**96.1**
Contact Year 11	94.7	96.2	95.3	96.2	**95.6**
Contact Year 12	93.9	97.0	94.9	97.2	**95.7**
Contact Year 13	91.6	97.3	93.8	97.0	**94.9**
Contact Year 14	91.6	96.7	93.0	96.6	**94.4**
Contact Year 15	91.4	97.4	92.2	96.2	**94.2**
Contact Year 16	90.9	97.6	91.6	96.0	**93.8**

Contact Year 17	89.7	97.9	91.2	95.0	**93.3**
Contact Year 18	88.0	97.7	90.2	94.8	**92.4**
Contact Year 19	86.6	97.3	89.9	94.4	**91.7**
Contact Year 20	86.5	96.4	89.5	94.5	**91.5**
Contact Year 21	86.1	94.6	90.0	93.9	**91.0**

B.1.d. Sample Size Requirements

For community surveillance, it is required that the combined communities be large enough to detect 2% annual changes in the incidence of definite fatal CHD and definite nonfatal MI over a nine year period. Using α=.05 and β=.20, the populations need to be large enough to generate 1120 cases per year. This requires a combined community population, aged 35-74 of 227,000 persons. In actuality, ARIC has a combined population, aged 35-74 of 279,000 persons. For the extended age group 75-84 years in CHD surveillance, 350 new cases per year in four communities would be needed to detect a 3% annual change in trend assessment. For hospitalized heart failure surveillance, 950 first heart failure cases per year would be needed to detect a 3% annual change in trend assessment. The combined population is sufficient to ensure a statistical power of 80 percent.

Secondly, for community surveillance, it is required that each community be large enough to detect the same two percent annual decline over a 10 year period. To achieve this, each community would need to be large enough to generate 350 new cases per year. This requires each community to have a population, aged 35-74 of 48,000. In actuality, all of the ARIC communities, except Washington County, exceed this 48,000. A lower population size was permitted for Washington County because mortality from CHD is much higher in Washington County than in the United States (36 percent higher for men, either percent higher for women). Thus, a sufficient number of cases will be generated. For the extended age group 75-84 years, approximately 60-110 CHD cases are needed for estimated three percent annual change, depending on community size. For hospitalized heart failure surveillance, 190-290 cases are needed for an estimated three percent annual change, depending on community size. All of the ARIC communities have sufficient population size for the planned analyses.

The sample size requirements for the Cohort population are as follows:

- Cohort populations in each community should permit calculating reasonably precise estimates of the proportion of cohort events missed by surveillance (and the number of events which surveillance falsely diagnosed as definite CHD).
- The combined cohort size should provide enough new events in three years for the prospective evaluation of the effects of risk factors.
- Cohort population in each community should be limited to the number of fasting participants in a single clinic that can examine in a three year period (six each working day = 4,000 in three years).
- A combined cohort size of 16,000 men and women aged 45-64 would be expected to include 15,086 participants free of CHD at entry (based on Framingham rates) and generate 471 CHD events in a three year follow-up. Even if incidence rates have declined since Framingham, there would be an adequate number of events for

evaluating effects of the more important risk factors in three years. Additional statistical power would be obtained from using ultrasound diagnosis as a dependable variable.

- Excluding angina, 279 new CHD events would be expected in three years of follow-up. The number of events available for validating surveillance (estimated by adjusting 279 for (1) the difference between Framingham and current rates and (2) the number of new events occurring among persons with prevalent CHD at entry) is 286.
- For the four cohorts, the expected number of events for validating surveillance is 71 in each (286/4). If surveillance missed 25 percent of the cohort events, 95 percent confidence limits around this estimate would be $\pm$ 10 percent. Confidence limits around the same estimate in the combined communities would be $\pm$ 5 percent.
- In a complex epidemiologic study such as ARIC, sample size calculations based on a simple comparison of one risk factor for cases and controls will tend to underestimate the sample size required. Risk factor analyses are usually more complex using covariate adjustment and statistical modeling. Thus, it is also instructive to determine the yield from existing studies of varying sample sizes. From the Framingham Heart Study, OMB # 0925-0216 (5,209 men and women followed for 30+ years), the Honolulu Heart Study, OMB #925-0122 (8,006 men followed for 12 years), and the Puerto Rico Heart Health Program, OMB #68-6444 (approximately 9,824 men followed for 12 years), there is experience showing that risk factor relationships can be detected with the expected number of events (471) occurring in ARIC over three years in the combined population.
- For the measurement of atherosclerosis by ultrasound, estimates of precision have been made. One measurement, the width of the atherosclerotic lesion as visualized in the artery, has a variance of 5.9 mm. Thus, to detect a difference of 1 mm between two groups at the baseline examination (i.e., men vs. women, or blacks vs. whites, or younger vs. older), each group must have at least 400 individuals (α=.05, β=.20). The Cohort sample satisfies this requirement.

B.2. Procedures for Information Collection

The procedures for follow-up and for community surveillance were explained in detail in the previous submission to OMB. They will be briefly summarized here since they are continuing.

B.2.a. Cohort Follow-up

Telephone follow-up of the ARIC cohort is used to maintain contact, to correct address information of cohort participants and to ascertain medical events between each contact. With the ARIC contract renewal, the frequency of calls will be increased from once to twice a year. The Annual Follow-up Questionnaire will be administered within 1 month of the anniversary date of the original visit, and Semi-Annual Follow-up Questionnaire will be given 6 months ($\pm$ 1 month) later.

A telephone interview is conducted unless the participant cannot be reached by telephone. A home interview is scheduled instead. The questionnaire queries information on hospitalizations for illness or surgery, diagnoses, medical care and symptoms. The participant is

asked about possible MI and heart failure diagnosis. Verification of address and phone number is made along with an update of the other information used to contact the participant. Every attempt is made to identify cohort participants who have died in advance of the telephone contact through regular review of obituaries and death certificates.

During the follow-up contact, the cohort participant may indicate that he or she has been hospitalized for a condition of interest to the study (CHD, peripheral vascular disease, cerebral vascular disease or heart failure). In these cases, the hospital record is identified and all relevant information becomes part of the participant's study data. The participants have signed a medical release form allowing the study to access medical records, but often the hospitals will require a recent or hospital specific release form which the study staff obtains.

Similarly, during the follow-up contact it may be determined that the participant has died. In these cases, the death certificate is obtained from the Vital Statistics registrars and the place of death determined. For in-hospital deaths, the hospital record is reviewed as indicated above. For out-of-hospital deaths and decedents admitted without a pulse rate or blood pressure, the participant's family is contacted to provide information on the circumstances surrounding the death. The participant has given consent to contract family members regarding the participant's illness or death.

The information on hospitalizations and deaths is reviewed and a determination of the occurrence of CHD, peripheral vascular disease and cerebral vascular disease is made according to defined criteria. Heart failure diagnosis will be added to our list of determinations beginning with 2005 events. Cause of death is also determined.

B.2.b. Community Surveillance

The Community Surveillance study currently provides measures of the geographic and temporal variation of atherosclerosis and CHD in four U.S. communities and will suggest reasons for the observed patterns. In each community, the study currently obtains a complete enumeration and valid diagnostic classification of the fatal CHD and hospitalized MI in a sample of all residents aged 35-74. Beginning with 2005 events, this age increased to 84 and heart failure was added to the community surveillance events.

Community Surveillance data gathering procedures for hospitalized MI and heart failure are based on a review of hospital records of a sample of all age-eligible residents with either a diagnosis of MI or heart failure or one of several screening diagnoses who were discharged from any of the acute care hospitals in the area. Review and abstraction of hospital records is conducted by study personnel, including the filing and return of records.

The surveillance of CHD deaths is accomplished by the review and abstraction of a sample of all age and residence eligible death certificates with various manifestations of CHD coded as the underlying cause of death during the study period. An additional subset of death certificates is sampled from a group of related high yield ICD codes. Sources of validation for out-of-hospital death, and dead-on-arrivals include interviews with the next-of-kin, and personal physician, coroner or medical examiner reports, and hospital records. Deaths occurring in the hospital are classified by abstracting information from the medical record. All CHD deaths

which are not positively classified by the diagnostic algorithm undergo review by a classification panel.

B.2.c. Fifth Clinical Examination of the Cohort

The fifth cohort examination will take place approximately 13 years after the date of the fourth examination. Each participant has been contacted annually, by telephone, since their first visit. Prior to their 25th annual telephone contact, they will receive a letter briefly describing the visit and indicating that they will be scheduled for the visit during the telephone interview. At the end of their usual interview, they will be asked whether there are medical reasons which would prohibit a fast, reminded to bring medications used in the prior two weeks, reminded to bring names and addresses of their physician and contacts, and scheduled for their clinic visit.

The general format for the fifth visit is very similar to the first through fourth visits. Though some specific items have been changed, the visit begins with reception and informed consent (**Attachment 1, Consent Forms**). Questionnaires are administered to collect information on demographics, access and quality of medical care, dietary intake, personal history, medical history, cognitive function, medication use, physical ability, and physical activity. Medical procedures are performed which include anthropometry, sitting blood pressure, ankle-brachial index, ECG, pulmonary function testing, physical function testing, echocardiography, and pulse wave velocity. The participant's findings will be reviewed and an exit interview will take place. As with the previous visits, abnormal findings will be relayed to the participant and his or her physician as previously agreed to by the participant. Copies of the forms are found in **Attachment 1**. A summary of the components of the fifth visit is found in **Table B.2.c.1**.

Table B.2.c.1. Components of the fifth examination

Section	Purpose
Mail recruitment	Describe the visit and notify the participant that he or she will be scheduled for the visit during the 25th annual telephone interview. (2 minutes)
Annual follow-up and Visit 5 scheduling	By telephone, ascertain vital status, general health, occurrence of specific cardiovascular events, hospitalizations, functional status and current tracking information. Schedule visit, determine whether medical reasons would prohibit a fast, and remind participant to bring medications used in the past two weeks. (15 minutes)
Reception	Greet the participant; re-explain the purpose of the study; obtain informed consent; explain the schedule; determine adherence to the fasting and abstinence protocols; update contact information; receive bag of medications from the participant and complete the medication survey form. (25 minutes)

Anthropometry	Measure height, weight, waist, hip, and bio-impedence. (4 minutes)
12-lead Electrocardiography	Obtain a 12 lead ECG on the participant. (20 minutes)
Sitting blood pressure	Measure systolic and diastolic blood pressure. (11 minutes)
Blood and urine collection	Obtain fasting blood and urine samples (10 minutes)
Laboratory analysis of blood specimens	Follow procedures to process whole blood, serum, plasma, and DNA. (0 minutes)
Ambulatory Electrocardiography (subgroup of n=500)	Obtain a holter monitor on 500 participants. (10 minutes)
Medical history and interview	Obtain interview data on demographic information, access and quality of medical care, dietary intake, personal history, medical history, cognitive function, medication use, physical ability, and physical activity. (71 minutes)
Pulse Wave Velocity	Measure arterial distensibility. (30 minutes)
Echocardiography	M-mode and 2-D Doppler measurements, tissue Doppler for measurement of left ventricular diastolic function and speckle tracking to measure global and regional myocardial function. (50 minutes)
Ankle-brachial index	Measure systolic blood pressure in ankle and arm to allow calculation of ankle-brachial index and determination of peripheral vascular disease. (20 minutes)
Pulmonary function test	Measure expiratory flow rates and vital lung capacity to identify participants with COPD. (30 minutes)
Physical functioning test	Fast walk test, chair stands, Jamar Hand Grip Strength. (15 minutes)
Participant results reports	Preliminary summary of findings outside expected range. (5 minutes)
Participant flow	Anticipated cumulative lag time to be accrued between components of clinical visit. (snack 10 minutes, other 15 minutes)

B.3. Methods to Maximize Response Rates and Deal with Non-response

B.3.a. Cohort Follow-up

As has been shown in **Table B.1.c.3**, ARIC has been successful in keeping participants active in this study. The response rate of the annual follow up at contact year 21 was 91.0% over

all centers. We anticipate maintaining this level of response in the future. To maintain high response to the annual telephone call the following procedures are done:

- Information on telephone numbers, addresses, and persons who would know the location of a participant were collected at ARIC Visit 1 and updated on subsequent contacts so that if a person has moved, ARIC can locate the participant.

- If the information for the annual follow-up cannot be obtained by telephone contact, then an interviewer will visit the household to obtain the information.

B.3.b. Cohort Examination

To maintain high response to the Cohort Examination (Visit 5), the following procedures are done:

- The initial recruitment for the return visit begins with an annual follow-up interview.
- An appointment to be seen in the clinic or at the participant's home or long-term care facility is scheduled at a convenient time, including Saturdays.
- Mail and telephone reminders of the appointment are sent to the participant.
- If a participant fails to attend at the appointed time, contact will be made and a convenient appointment scheduled.
- Payment for transportation by taxi or other means is offered for the examinations in the clinic.
- To trace persons who have moved, all letters are sent marked "forwarding and address correction requested." Tracing procedures include contacting friends, neighbors, and relatives listed by the participant on follow-up phone calls.
- All centers have had cooperation and coordination with physicians and community groups to foster acceptance of the study in each community. All study interviewers and recruiters are trained in interviewing techniques.

B.4. Tests of Procedures or Methods to be Undertaken

The clinical examination questionnaires submitted for OMB review have been pre-tested at our field centers in similar aged volunteers as the present ARIC Cohort. Questionnaires and procedures that have been administered at previous ARIC Cohort examinations have been refined previously to minimize burden and improve utility. After OMB and IRB approval, and after central training occurs, the entire examination will be pilot tested in each field center on no more than 10 volunteers. The pilot study is required to refine all procedures, clinic scheduling, interviewer techniques, and center coordination in advance of full implementation of the examination. Substantive changes resulting from the pilot testing will be forwarded to OMB as soon as available.

B.4.a. Standardization and Quality for Collection Methods

Rigid standardization procedures have been developed and implemented for all aspects of ARIC in recognition of the intricacies of running long-term, multi-center collaborative field studies. ARIC is unusual in its composition in that it contains a number of organizations to standardize and monitor the collection of data in addition to the field centers. An ECG reading center at Wake Forest University, School of Medicine, provides training/recertification and

readings of electrocardiograms and holter monitors. A Central Hemostasis Laboratory at the University of Minnesota provides centralized determinations of hemostasis factors and a Central Lipid Laboratory located at Baylor College of Medicine provides standardized lipid and lipoprotein measurements. Central Pulmonary Function (by Pulmonary Expert Team members, Paul Enright, John Hankinson, Graham Barr) and the Clinical Chemistry (University of Minnesota) Laboratory provide ARIC with standardized measurements and quality assurance criteria. The ARIC Coordinating Center (CSCC at the University of North Carolina) provides overall coordination of study design, study management, data management, and statistical analysis.

Blood samples are drawn at the field centers, shipped on dry ice to the individual laboratories according to a standard protocol, and processed according to standard protocols specifically designed for this study at the separate central facilities. Central training and recertification for all ARIC phlebotomists is done by ARIC personnel at the Hemostasis Laboratory in Houston. Blinded quality control samples for all blood work are drawn and processed routinely. Laboratory results are transferee to the Coordinating Center which provides the study with recommendations for equipment, a standard protocol, centralized training/recertification and quality control monitoring. The ECG Reading Center provides equipment recommendations, standard protocols, centralized training/recertification, and quality control assessment. ECGs on cohort participants are centrally read at the Reading Center. The Coordinating Center has prepared standard data collection instruments and instructions for use at all four field centers. It provides central training and recertification for all data coordinators and field interviewers in interviewing techniques, data collection procedures using the distributed data entry system and paper forms, physical examination procedures. The Coordinating Center monitors recruitment and cohort follow-up status with quarterly reports to principal investigators. The Coordinating Center is providing the field centers with a data management system, supported by consistent hardware and software, which facilitates the standard collection of data by field center and central agency staff in different locations. Computer-assisted data entry benefits from real-time validation checks. Clinic monitoring is an integral function of the Coordinating Center which provides the ARIC advisory board with quality reports and organizes the field center and support agency site visits to assess adherence to the protocol.

B.4.b. Standardization and Quality Control for the ARIC Examination

For each ARIC examination, identical equipment is purchased for use at each Field Center. Each piece of equipment is calibrated using identical standards. In addition, technician training and performance is standardized. Training is done centrally by the designated Central lab, Reading or Coordinating Center. Uniform manuals of operations and training manuals are used. Technicians and interviewers are tested and certified as capable of performing the taskes according to protocol. The central trainers visit each field center periodically to determine whether the protocol is being followed. Finally, laboratory, pulmonary tests, and ECGs are analyzed at a central site. Bloods are collected at each field center and sent to the three laboratories for analysis of lipid, hemostasis factors, and chemistry.

To monitor the data quality over time, a variety of techniques are used:

- Equipment is routinely calibrated over the length of the examination
- Technicians are retrained and recertified at fixed intervals
- Random visits are made by the project office and those supervising the quality control procedures
- Field supervisors provide oversight
- Portions of the laboratory and examination are repeated for a sample of participants
- Means and distributions of collected data are analyzed by Field Center and technician, and for change over time
- Measures are collected expressly for quality control assessment (e.g., time to fill first tube for phlebotomist assessment)

A quality control committee has been established to monitor the quality and standardization of all aspects of ARIC. This committee reviews procedures, evaluates site visit and monitoring reports, and studies quality control analyses which document performance. The committee recommends changes in procedure, calibration and training when warranted.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Paul Sorlie, Ph.D.	NHLBI, DCVS, EB National Institutes of Health (301) 495 0456
Lloyd Chambless, Ph.D. Diane Catellier, DrPH	Department of Biostatistics, University of North Carolina School of Public Health (919) 962-3264 (919) 966-1895

Contractors responsible for the data collection at the field centers:

Forsyth County, NC	Department of Epidemiology, University of North Carolina
Gerardo Heiss, M.D., Ph.D.	School of Public Health
Principal Investigator	(919) 966-3253, and Department of Comarative Medicine

	Bowman Gray School of Medicine
Jackson, MS Tom Mosley, M.D. Principal Investigator	Department of Medicine University of Mississippi (601) 984-5610
Minneapolis, MN Aaron Folsom, M.D. Principal Investigator	Department of Epidemiology University of Minnesota (612) 624-9950
Washington County, NC Josef Coresh, M.D., Ph.D Principal Investigator	Department of Epidemiology Johns Hopkins School of Hygiene and Public Health (410) 955-0495