Supporting Statement A for

The Jackson Heart Study (JHS): Annual Follow-up with Third Party Respondents (NHLBI)

OMB# 0925-0491

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Summary of the Jackson Heart Study (JHS)

The Jackson Heart Study (JHS) is a collaborative research initiative between the National Institutes of Health's (NIH) The National Center on Minority Health and Health Disparities (NCMHD) and the National Heart Lung and Blood Institute (NHLBI) in the Jackson, MS area. The JHS is being conducted under NIH Clinical Exemption (CE-99-11-09). This request is for clearance for contact of next-of-kin and family physicians of deceased participants who were part of the JHS Exam (OMB No. 0925-0491, expiration 8/31/2010)

The objectives of the JHS are both scientific and operational. The primary scientific objective is to investigate genetic and environmental causes of the disproportionate burden of cardiovascular disease (CVD) in African-Americans and to learn how best to prevent these diseases. The operational objectives are to build research capabilities in minority institutions, address the critical shortage of minority investigators in epidemiology and prevention, and reduce barriers to dissemination and utilization of health information in a minority population.

The JHS is uniquely positioned to investigate CVD risk factors, especially manifestations related to hypertension such as coronary artery disease, heart failure, stroke, peripheral arterial disease, and renal disease. Recruitment of 5,500 JHS participants began in September 2000 and was completed in March 2004. Roughly 1,600 Jackson ARIC participants joined the JHS, while 1,300 participants were family members of roughly 220 cohort probands. 5,301 participants completed a baseline exam that included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, carotid ultrasonography, echocardiography, and pulmonary function.

Negotiations for the continuation of the JHS were completed on June 15, 2005. Two new exams include some repeated measures from Exam 1 and several new components,

including distribution of self-monitoring blood pressure devices. JHS Exam 2 began in October 2005, followed by a more comprehensive Exam 3 that began in February 2009. During clinical Exam 2, which ended in December 2008, 4,205 JHS participants were examined. The data collection phase of Exam 3 is currently in progress. The target number of participants for the Exam 3 components are: 4250 participants for the core clinical examination (85% retention rate), 4500 participants for CT scans, and 2500 participants for the cardiac MRI studies.

In order to achieve the operation objective of the study, Tougaloo College has developed a training program in the past 5 years. Undergraduates are actively participating in public health coursework including annual summer short courses in Epidemiology, hands-on training within the study, and summer internships at other public health settings. Further, high school students have participated in summer science, language, and math (SLAM) enrichment programs with an epidemiology and prevention focus. These students and health professionals are already bringing their unique perspectives to the study and helping to ameliorate the shortage of minority investigators in epidemiology and prevention.

Justification

A.1 Circumstances Making the Collection of Information Necessary

The Jackson Heart Study: Annual Followup with Third Party Respondents involves contact with informants (next of kin) and physicians of the out-of-hospital deaths in the community. The three counties (Hinds, Madison, and Rankin) will be under surveillance for the occurrence of hospitalized cardiovascular disabilities in African-Americans aged 21-84. A review of hospital records will be done on a sample of all age-eligible residents of the communities with a discharge of myocardial infarction or one of several related screening diagnosis codes. A review will be done on a sample of all age-eligible and residence-eligible death certificates with various manifestations of CVD coded as the cause of death. For deaths not occurring in a hospital, the decedent's physician and next-of-kin will be queried about the circumstances around the time of death. The JHS will fulfill a major research need to understand more completely the determinants of cardiovascular disease and death.

The objective of this information collection is within the National Heart, Lung, and Blood Institute (NHLBI) mandate described in the Public Health Service Act, Section 421 (42 USC 285b-3 specifies the provision of: (A) investigation into the epidemiology, etiology and prevention of all forms and aspects of heart, blood vessel, lung and blood disease, including investigations into the social, environmental, behavioral, nutritional, biological and genetic determinants and influences involved in the epidemiology, etiology and prevention of such diseases.

The excessive burden of heart disease and stroke continue to be major unanswered problems in the African-American population. Although death rates of CVD disease have declined overall in the last 25 years, death rates for CVD in the U.S. are considerably higher

among African-Americans than in Whites, and CVD death rates for both groups in Mississippi are the highest in the nation. The search for answers has primarily utilized traditional epidemiologic principles with black and white comparisons. This approach has failed to completely explain either the difference in hypertension rates or the high cardiovascular disease mortality rates among African-Americans. The JHS was initiated in 1998 to study cardiovascular disease in African-American adults living in the Jackson MS,Metropolitian area.

High prevalence of traditional risk factors identified in previous studies may account for some of the excess cardiovascular disease morbidity and mortality in African-Americans. Hypertension, one of the most common CVD risk factors, is particularly important in African Americans because it is more frequent, severe, and develops at an earlier age than in Whites. Hypertensive target organ damage, such as renal failure and left ventricular hypertrophy, are more common in black than in white hypertensive individuals at comparable levels of blood pressure. Many other risk factors are also more common in blacks, including Type II diabetes, increased lipoprotein levels, and obesity (in women). Body composition and fat distribution differ substantially between African-Americans and Whites and may be related to the greater incidence and severity of metabolic syndrome and diabetes in African-Americans. The data demonstrate high prevalence of risk factors: 62% of recruited JHS participants are hypertensive, 59% of the women and 43% of men are obese (BMI > 30kg/m2), and 30% have the metabolic syndrome.[1] Exploration of the impact on and interaction of high risk factor levels with other measures of clinical and subclinical disease will help identify unique approaches to reducing the disproportionate burden of CVD in African-Americans. Hypertension and obesity are modifiable CVD risk factors associated with increased prevalence and severity of CVD in

1 (Taylor HA, Jr., Wilson JG, Jones DW, Sarpong DF, Srinivasan A, Garrison RJ et al. **Toward resolution of cardiovascular health disparities in African Americans: design and methods of the Jackson Heart Study.** Ethn Dis 2005; 15(4 Suppl 6):S6-17.)

African-Americans that may contribute most to the racial disparity between African-American and White populations.

A.2. Purpose and Use of the Information Collection

The primary purpose of The Jackson Heart StudyAnnual Followup with Third Party Respondents is to obtain reliable information from next of kin and physicians of deceased participants to identify the causes of subsequent morbidity and mortality. To identify the factors which influence the development of CVD in African-Americans and which promote improved health in the JHS, follow up is necessary to understand the impact of the JHS interventions. Specific contact with the next of kin and physicians is the most effective method of data collection. It can be supplemented by actual information abstracted from medical records and death certificates**.** There were 20 publications and 104 presentations in the last three years.

A.3. Use of Information Technology and Burden Reduction

Information technology is not utilized because the annual burden reduction on approximately 200 physicians or next of kin is not cost effective.

A.4. Efforts to Identify Duplication and Use of Similar Information

The JHS contains many research components that are being employed for the first time in a comprehensive African-American adult population with high incidence of CVD. The follow-up study, therefore, does not duplicate information obtained in other studies. Because this is a study of a newly formed cohort, only limited information on the original participants is available and that will not be duplicated in the clinical portion of the study, but limited only to new recruits. Follow-up information on all participants represents information not otherwise available.

Because JHS represents a unique group, this proposed follow-up does not duplicate other

studies.

A.5. Impact on Small Businesses or Other Small Entities

Physicians constitute the only small business burdened by the JHS. They are requested to provide medical information on selected patients identified by the study. These requests are limited only to essential information needed to determine the presence of cardiovascular conditions. This information collection will not have a significant impact on a substantial number of small entities.

A.6. Consequences of Collecting the Information Less Frequently

The JHS Follow-up study will collect information on deceased participants from the next of kin and physicians a single time.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to the information collection.

A.8. Comments in Response to the **Federal Register** Notice and Efforts to Consult Outside Agency

A copy of the **Federal Register** notice, dated January 13, 2010, and published in Volume 75, Number 8, page 1789, wherein public and affected agencies comments were solicited, is appended. No comments were received during the 60-day comment period.

The JHS initiative was developed by the Division of Prevention and Population Sciences (formerly, Division of Epidemiology and Clinical Applications) to address recommendations of the 1994 NHLBI Task Force on Research in Epidemiology and Prevention of CVD, the 1995 Special Emphasis Panel on Longitudinal Cohort Studies, and the 2002 NHLBI Strategy for Addressing Health Disparities. The NHLBI Advisory Council supported the JHS initiative at its May, 1997 and October 2003 meetings. Copies of the appropriate sections of the minutes (from

the Oct. 2003 meeting) are appended (**Attachment #1**). The NHLBI Advisory Council is composed of non-government health professionals and researchers and provides final review of NHLBI research.

In addition, the members of the JHS/NHLBI Observational Studies Monitoring Board (OSMB) met annually from 1998 to 2003 to advise on the progression to the full JHS examination visit. The OSMB has continued to meet annually to give advice on the design, procedures, and analysis of the JHS. The roster **(Attachment #2)** of the JHS OSMB and meeting minutes from the previous 3 years **(Attachments #3-5)** are enclosed as **Attachments**. A nine-year continuation of the study was strongly endorsed by an outside Advisory Panel convened in May 2003. (**Attachment #6**).

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents in this Surveillance phase.

A.10. Assurance of Confidentiality Provided to Respondents

All JHS Principal Investigators and their institutions have agreed to comply with the Federal Privacy Act as part of their contractual agreement with the NHLBI. The contract stipulates that research involving human subjects cannot be conducted until 1) protocol has been approved by NHLBI, 2) written notice of such approval is provided by the Contracting Officer, and completed Form SF-310 certifying Institution Review Board (IRB) review and approval of the protocol (see **Attachment #7**).

A.10.a. Data Collection

Data collection forms completed in the participant homes are edited and entered into the tracking system by Examination Center staff. Completed data collection forms, including consent forms, are keyed at the Data Management, Information Technology & Quality

(DMITQA) unit using the Epi Info7 software. The JHS data management system uses a local area network to connect workstation microcomputers or laptops to a local database computer. This adds a level of confidentiality since a user must have a special ID and password to log on to the network in order to gain access to the data management system. Data collected will only have a survey identification number. In addition, another level of security is function-specific, so that interviewers are only be allowed to access the specific interviews they are assigned, and staff performing editing, analysis, etc. will have another function-specific ID and password. Data is backed-up after each interview is completed, and daily back-ups are performed to the network server to minimize data loss.

A.10.b.DMITQA Unit: Security and Confidentiality

All DMITQA staff are instructed in procedures for maintaining data confidentiality, and sign a form indicating their awareness of maintaining confidentiality of data. Staff are also informed that any inappropriate use or disclosure of confidential data is cause for immediate termination of employment at the DMITQA. All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigators maintain data security and confidentiality in accordance with guidelines of the NIH.

Since this is a single study site, the data are entered quickly after collection and will not leave the premises. The DMITQA maintains a secure room where original data are stored in locked file cabinets. This room is locked at all times and only selected members of the staff have access. Electronic back-up of the data is made on a regular basis. The DMITQA has procedures for disposal of confidential data, as defined by any medium containing masked information or personal identifiers. Biological samples from participants are identified only by

Study ID number.

Data are only being made available to persons performing statistical analysis. If outside consultants or investigators with offices outside the study site need access to the data for publications, a data tape is prepared with no personal identifiers included.

In publications, the individual identities of participants are not disclosed, and data are reported only in the aggregate. Information obtained from the study will be included in the Privacy Act System of Records 09-25-0200, entitled, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" as published in the Federal Register, Vol. 67, No. 187, pps. 60776-60780, September 26, 2002.

A.11. Justification for Sensitive Questions

There are no sensitive questions contained in the informant contact questionnaire and physician contact questionnaire for the surveillance phase of the JHS.

Informant interviews and physician interviews for cardiovascular and stroke disease deaths will be conducted with informants and physicians previously designated by the participant to determine the circumstances surrounding a participant's death. The information from these interviews is critical in determining whether or not a death was due to cardiovascular or stroke causes, which are the primary endpoints of the study. Respondents have been fully informed in writing about the nature of the study, the voluntary aspects of their participation, benefits from participation, risks associated with participation, and the extent to which confidentiality of identifiable information can be assured.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

The estimate for respondent burden for the Follow-up component is presented in Table A.12-1 below. These estimates represent annual burden.

Table A.12-1 Estimates of Annual Reporting Burden to Respondents

Type of Respondents	Number of Respondents	Frequency of Responses	Average Time Per Response	Annual Hour Burden
Families	200	1	0.17	34
Physicians	200	1	0.25	50
TOTAL	400	---------	----------	84

The annualized cost of $3,760 assumes $15 per burden hour for informants and $65 per burden hour for physicians.

Table A.12-2 Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Responses	Average Time Per Respondents	Hourly Wage Rate	Respondent Cost
Families	200	1	0.17	$15.00	510
Physicians	200	1	0.25	$65.00	3250
TOTAL	400	---------	----------		3760

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no Capital Costs, Operating Costs, or Maintenance Cost to this report.

A.14. The Annualized Cost to the Federal Government

The average annualized cost to the U.S. Government for the information collection in the JHS is $6,003,000 per year. This is itemized as follows:

Table A.14-1 The Annualized Cost to the Federal Government in Information Collection

	Personnel	Equipment	Subcontract	Other	Overhead	Total
JHS Examination Center and DMITQA	$2,854,000	$75,000	$1,488,000	$929,000	$657,000	$6,003,000

The annualized cost of monitoring the project by the National Heart, Lung and Blood Institute is estimated at $456,000.

Table A.14-2 The Total Annualized Cost to the Federal Government

	Information Collection	Monitoring	Total
JHS Examination Center and DMITQA	$6,003,000	$456,000	$6,459,000

The total annualized cost of the project is estimated at $6,459,000.

A.15. Explanation for Program Changes or Adjustments

The number of respondents listed in the previous OMB submission were predicted estimates. The number of respondents listed in the current submission are adjusted based on mortality rates during the past three years. One will notice that the number of respondents in the

current submission are less than the number in the previous submission. This is primarily due to the overestimation of mortality rates in our previous submission. The burden hours and respondent cost are also significantly less in this submission as compared to the previous submission.

The annualized cost to the federal government has also increased slightly due to a 3 percent annual inflation/escalation rate.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The JHS staff will collect the information after obtaining OMB approval. The DMITQA computing staff will then analyze the collected information in a timely manner after the necessary data editing has been done, and after the data quality control procedures have verified that collection procedures operated properly. The following timetable for data collection and analysis, in terms of the time elapsed following OMB approval, is presented in Table A.16-1.

Table A.16-1 JHS Time Schedule

	Activity	Time Schedule
Exam 2	Analysis/Publication	~2 weeks after OMB approval
Exam 3	Participant contact/ clinic scheduling	~2 weeks after OMB approval
	Data collection	~2 weeks after OMB approval
	Data closeout	~18 months after OMB approval
	Analysis/Publication	~30 months after OMB approval
Contract Renewal	Negotiations with NHLBI / NCMHD	~20 months after OMB approval

To achieve the ultimate goal of determining policy recommendations for cardiovascular disease prevention, the intermediate goal is to present statistical results by publishing in scientific journals (e.g. New England Journal of Medicine, Journal of the American Medical Association, Circulation, American Journal of Human Genetics, Diabetes Care, Hypertension), by presentation at scientific meetings (e.g., American Heart Association, Council on Cardiovascular Epidemiology, American Public Health Association, International Genetics Epidemiology Society Conference, American Society of Human Genetics), and by compilation of special reports and monographs available to the scientific community. JHS publication guidelines have been written to foster the analysis and publication of data. The reports on morbidity and mortality from next of kin and physicians and medical records are to be used to determine the cause of death of the participants.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption is not requested. Displaying the OMB expiration date is appropriate for this submission, and will be printed on the JHS documents.

A.18. Exceptions to Certification for Paperwork Reduction Act Submission

The data encompassed by this study will fully comply with all guidelines of 5 CFR 1320.8(b)(3) and no exception is requested to certification for Paperwork Reduction Act Submission.