

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 Institute on Minority Health and Health Disparities (NIMHD) 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 revision/program change clearance request is for:**

- 1) **Contact with next-of-kin and family physicians of deceased participants who were part of the JHS Exam (OMB No. 0925-0491, expiration 6/30/2013).**
and
- 2) **Data collection from community members by JHS Community Health Workers.**

The Jackson Heart Study (JHS) is a multi-center investigation of predictors of cardiovascular disease (CVD) in 5301 African Americans living in Hinds, Madison, and Rankin Counties surrounding the Jackson, MS, metropolitan area. The JHS was initiated in 1998 as a collaborative effort among three Jackson-area academic institutions. At the close of the current contracts in May 2013, the JHS will have completed three back-to-back cohort examinations that have produced extensive longitudinal data on traditional and putative CVD risk factors, socioeconomic and sociocultural factors and biochemical analytes; measures of subclinical disease from echocardiography, cardiac magnetic resonance imaging (MRI), computed tomography (CT) scans of the heart, aorta and abdomen; and stored biological samples. Eighty percent (80%) of the surviving JHS participants (N = 4203) completed Exam 2; projected retention for Exam 3 is eighty-six percent (86%) (N = 4082). In addition, the JHS has conducted annual cohort follow-up contacts for incident clinical events of interest, a variety of community education and outreach activities to promote healthy lifestyles to reduce disease risk

burden, and level-appropriate training programs to promote and support public health research.

The JHS represents an expansion of the Jackson Field Center of the Atherosclerosis Risk in Communities (ARIC) study, to broaden data collection in an African American population and to increase access to and the participation of African American populations and scientists in biomedical research and professions. A total of 15,792 individuals were initially examined for ARIC, of which 3,732 were enrolled at the Jackson site. When the JHS began, it invited all previous Jackson ARIC participants, who were approximately 59 to 78 years of age, along with younger and older African American residents from a larger Jackson geographic area, to participate in the new cohort study. Due to JHS' shared cohort membership with ARIC, the two studies cooperate with each other in data analysis and on events validation for members of the two cohorts.

JHS is currently in its third clinical examination. Exam 3 clinical data collection was extended to January 2013 and MRI scans have been extended until December 2012. The study is in the middle of its contract renewal and renewal is expected. The renewal of the JHS will have a companion RFA, focusing on increasing scientific productivity; mainly bringing in outside/experienced investigators to collaborate with JHS on additional analyses and publications of findings into high impact journals. These collaborations will also provide a great mentoring opportunity for the Jackson investigators.

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.

Community Health Advisor Networks (CHANs) comprise another component of the Study. Most Mississippians have at least one risk factor associated with CVD. The CHANs address CVD prevention through health education programs in five Mississippi communities. Community Health Advisors (CHAs) are trained and certified to organize and implement various programs in their communities (**Attachments #1-5**) (<http://jhs.jsums.edu/jhsinfo/Community/CommunityHealthNetwork/tabid/74/Default.aspx>). The "With Every Heartbeat is Life" Training (or training that uses the "Your Heart, Your Life" Manual) requires participants take pre- and post-training exams to assess pre- and post- test behavioral changes during some sessions. Jackson Heart Study CHAs are also assessed to ensure that they participate, coordinate, or conduct health education programs in the community.

The CHANs meet 10 times a year on average, from September through June. The forms administered during the meetings take an average of 90 minutes to complete.

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, Metropolitan area.

The primary goals of the JHS are both scientific and capacity building. The scientific goals are to identify factors related to development and progression of CVD and its risk factors in Jackson-area African-Americans; and to assess roles of sociocultural and hereditary factors, specific genetic variants, and gene-environment interactions in CVD. The capacity building goals are to enhance research capabilities in minority institutions, address the critical shortage of

minority investigators in epidemiology and prevention research, and reduce barriers to dissemination and utilization of health information in a minority population.

In the JHS, between Exam 1 and 2 hypertension increased from 63% to 73%; diabetes increased from 19% to 29%; and obesity (BMI >30kg/m²) increased from 53% to 56%, with 30% having metabolic syndrome at both exams. Preliminary computed tomography (CT) results show 47% of participants have evidence of subclinical CAD; in the abdominal aorta 65% of participants have measurable calcified plaque. There is ample evidence that the burden of disease in the African American population is high but there is a lack of clear understanding of the relative prevalence and importance of a variety of risk factors, including behavioral origins, interrelationships among risk factors, and genetics. 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 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 Study Annual Follow-up 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.

Promoting CVD prevention through health education program is another objective of the study. Interactions of Community Health Advisors (CHAs) with the community need to be recorded. Further, the activities of the CHAs conduct also need to be followed to ensure that the programs are reaching the community.

The JHS has 130 papers published or in press; 22 active ancillary studies; 10 collaborating data sharing external research centers and membership in multiple genetic consortia funded through NHLBI, NIDDK and NHGR.I. Additionally, the 2010 JHS Tenth Anniversary Celebration/Scientific Sessions brought together scientists from many fields, young investigators, local practitioners, students, JHS participants, and community members which generated recommendations for future study.

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 October 24, 2012, and published in Volume 77, Number 206, page 65001-2, 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 2012 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 meeting minutes from the previous 3 years are enclosed as Attachment #1.**

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.

A.10.a. Data Collection

Data collection forms completed in the participant homes are edited and entered into the tracking system by Field Center (FC) staff. Completed data collection forms, including consent forms, are entered by the Coordinating Center staff 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. Security and Confidentiality

All staff is instructed in procedures for maintaining data confidentiality, and sign a form indicating their awareness of maintaining confidentiality of data. Staff is also informed that any inappropriate use or disclosure of confidential data is cause for immediate termination of employment. 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 secure room is maintained 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 JHS 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 Certificate of Confidentiality (Attachment #7) was obtained to assure confidentiality and privacy to JHS participants.

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	Form Name	Number of Respondents	Frequency of Responses	Average Time per Response	Annual Hour Burden
Families	Known Informant Letter Unknown Informant Letter Informant Interview (IFI) Form	200	1	10/60	33
Physicians	Physician Questionnaire (PHQ) Form	200	1	15/60	50
Communities:					
Bolton	For all Communities: Pre-Post Testing Forms for Community Health Advisory Networks (CHANs)	16	10	90/60	240
Canton	My Habits Pre-Post Test Community Health Advisor (CHA) Diary Train the Trainer Pre-Post Test	14	10	90/60	210
Clinton	Checklists	13	10	90/60	195
Jackson		15	10	90/60	225
Rankin		20	10	90/60	300
TOTAL		478	-----	-----	1253

The annualized cost of \$24,206 assumes \$17 per burden hour for informants and \$75 per burden hour for physicians.

Type of Respondents	Number of Respondents	Frequency of Responses	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
Families	200	1	10/60	\$17.00	\$566.00
Physicians	200	1	15/60	\$75.00	\$3,750.00
Community	78	10	90/60	\$17.00	\$19,890.00
TOTAL	478	-----	-----	-----	\$24,206.00

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 of the project in the JHS is estimated at \$6,849,000 per year. This is itemized as follows:

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

	Personnel	Equipment	Subcontract	Monitoring	Other	Overhead	Total
JHS CORC, FC and CC*	\$3,027,000	\$79,000	\$1,578,000	\$483,000	\$985,000	\$697,000	\$6,849,000

CORC=Community Outreach Center
 FC = Field Center,
 CC= Coordinating Center

A.15. Explanation for Program Changes or Adjustments

The number of respondents listed in the previous OMB submission was predicted estimates. In the current submission, the number of respondents, burden hours, and respondent cost has increased due to the addition of a new group of respondents, the Community Health Advisors. The annualized cost to the federal government has also increased.

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

The JHS staff will collect the information after obtaining OMB approval. The Coordinating Center (CC) 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 Period 3	Participant contact/ clinic scheduling	Ongoing
	Data collection	Ongoing
	Data closeout	~May 2013
	Analysis/Publication	Ongoing
Contract Renewal	Negotiations with NHLBI / NIMHD	~March 2013
Exam Period 4	Annual Follow-up/Certification	June 2013
Community Health Advisor	Training/Certification	~1 month after OMB approval
	Implementation of Health Education Programs	~2 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.

References

Reference for physician salaries:

<http://swz.salary.com/SalaryWizard/Physician-Generalist-Salary-Details-Jackson-MS.aspx>

Reference for U.S. Bureau of Labor Statistics(BLS):

<http://www.bls.gov/ncs/ocs/sp/ncbl1661.pdf>