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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

The Atherosclerosis Risk in Communities Study (National Heart Lung and Blood Institute).

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Jacqueline Wright, 6701 Rockledge Drive, MSC 7936, Bethesda, MD

20892, or call non-toll-free number (301) 435-0384, or E-mail your request to:

jacqueline.wright@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Atherosclerosis Risk in Communities Study, 0925-0281, REVISION, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The ARIC study was initiated in 1985 to examine the major factors contributing to the occurrence of and the trends for cardiovascular diseases among men, women, African Americans and white persons in four U.S. communities: Forsyth County, North Carolina; Jackson, Mississippi; suburbs of Minneapolis, Minnesota; and Washington County, Maryland. The cohort in Jackson is selected to represent only African American residents of the city. The primary objectives of the study are to: 1) investigate factors associated

with both atherosclerosis and clinical cardiovascular diseases and 2) measure occurrence of and trend in coronary heart disease (CHD) and relate them to community levels of risk factors, medical care, and atherosclerosis. Some specific activities for this revision of ARIC are continued telephone follow-up of the ARIC cohort, with twice yearly calls to identify new cardiovascular events and hospitalizations, update information about risk factors, and obtain information on access to and use of medical care for heart failure risk factors and heart failure, and to re-examine the surviving ARIC cohort (target n = 5,300) over a 21-month period.

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 23,289.

Estimated Annualized Burden Hours

| Type of Response | Number of Respondents | Number of Responses per Respondent | Average Time per Response (hours per year) | Total Annual Burden Hour |
|---|-----------------------|------------------------------------|--|--------------------------|
| Participant | | | | |
| a. Recruitment and Phone contact (Attachment 1) | 7,903 | 1 | 15/60 | 1,976 |
| b. Clinic examination (Attachment 7) | 5,572* | 1 | 100/60 | 9,287 |
| c. Annual Follow-up Form (Attachment 8) | 7,903 | 6 | 8/60 | 6,322 |
| d. Semiannual Follow-up Form (Attachment 9) | 7,903 | 6 | 7/60 | 5,532 |
| Subtotal (participant) | 7,903--- | 108,311 | – | 23,117 |
| Non-Participant | | | | |
| a. Coroner/Medical Examiner Form (Attachment 10) | 372 | 1 | 10/60 | 62 |
| b. Informant Interview Form (Attachment 11) | 372 | 1 | 10/60 | 62 |
| c. Heart Failure Survey (Attachment 12) | 100 | 1 | 10/60 | 17 |
| d. Physician Questionnaire Form (Attachment 13) | 372 | 1 | 5/60 | 31 |
| Subtotal (non-participant) | 1,216 | 1,216– | – | 172 |
| Total (Participant and Non-participant) | 9,119 | 109,527 | – | 23,289 |

* Participants included in item a.

Dated: October 31, 2016

Valery Gheen

NHLBI Project Clearance Liaison

National Institutes of Health

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