

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted Household Report-Long Form .....	52	1	35	1,820
Assisted Household Report-Short Form .....	140	1	1	140
Applicant Household Report .....	52	1	13	676

*Estimated Total Annual Burden Hours: 2,636.*

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, attn: ACF Reports Clearance Officer. E-mail address: [rsargis@acf.hhs.gov](mailto:rsargis@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Dated: August 22, 2006.  
**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 06-7190 Filed 8-25-06; 8:45 am]  
**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; The Atherosclerosis Risk in Communities Study (ARIC)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection:*  
*Title:* The Atherosclerosis Risk in Communities Study (ARIC).  
*Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925-0281).

*Need and Use of Information Collection:* This project involves annual

follow-up by telephone of participants in the ARIC study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women.

*Frequency of Response:* The participants will be contacted annually.

*Affected Public:* Individuals or households; businesses or other for profit; small businesses or organizations.

*Type of Respondents:* Individuals or households; doctors and staff of hospitals and nursing homes.

*The annual reporting burden is as follows:*

*Estimated Number of Respondents:* 12,845.

*Estimated Number of Responses per Respondent:* 1.0.

*Average Burden Hours Per Response:* 0.242.

*Estimated Total Annual Burden Hours Requested:* 3,108.

The annualized cost to respondents is estimated at \$60,525, assuming respondents time at the rate of \$16.5 per hour and physician time at the rate of \$75 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN (2007-2010)

Type of response	No. of respondents	Frequency of response	Average hours per response	Annual hour burden
Participant Follow-up .....	11,500	1.0	0.2500	2,875
Physician (or coroner) <sup>1</sup> .....	945	1.0	0.1667	158
Participant's next-of-kin <sup>1</sup> .....	450	1.0	0.1667	75
<b>Total</b> .....	<b>12,845</b>	<b>1.0</b>	<b>0.2420</b>	<b>3,108</b>

<sup>1</sup> Annual burden is placed on doctors, hospitals, and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Hanyu Ni, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number 301-435-0448 or e-mail your request, including your address to: [NiHanyu@nhlbi.nih.gov](mailto:NiHanyu@nhlbi.nih.gov).

*Comments Due 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.

Dated: August 21, 2006.

**Meg Scofield,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request; The REDS-II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

#### **Proposed Collection**

*Title:* The REDS-II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors.

*Type of Information Collection Request:* New.

*Need and Use of Information Collection:* Although the overall health significance of iron depletion in blood donors is uncertain, iron depletion leading to iron deficient erythropoiesis and lowered hemoglobin levels results in donor deferral and, occasionally, in mild iron deficiency anemia. Hemoglobin deferrals represent more than half of all donor deferral, deferring 16% of women. Several cross sectional studies of blood donors, using older measures of iron status in blood donors have indicated that female sex, frequent donation and not taking iron supplements are predictors of iron depletion. However, none of these studies have included racial/ethnic, anthropomorphic, or behavioral factors and none have evaluated the impact of newly discovered iron protein polymorphisms. The REDS-II Donor Iron Study is a longitudinal study of iron status in two cohorts of blood donors: A first-time/reactivated donor cohort in which baseline iron and hemoglobin status can be assessed without the influence of previous donations, and a frequent donor cohort, where the cumulative effect of additional frequent blood donations can be assessed. Each cohort's donors will donate blood and provide evaluation samples during the study period. We also propose to assess the baseline status of a group of first-time donors who are deferred for low hemoglobin on their first visit.

The primary goal of the study is to evaluate the effects of blood donation intensity on iron and hemoglobin status and assess how these are modified as a function of baseline iron/hemoglobin measures, demographic factors, and reproductive and behavioral factors. Hemoglobin levels, a panel of iron protein, red cell and reticulocyte indices will be measured at baseline and at a final follow-up visit 15-24 months after the baseline visit. A DNA sample will be obtained once at the baseline visit to assess three key iron protein polymorphisms. Donors will also complete a self-administered survey assessing past blood donation, smoking history, use of vitamin/mineral supplements, iron supplements, aspirin, frequency of heme rich food intake, and, for females, menstrual status and pregnancy history at these two time points. This study aims to identify the optimal laboratory measures that would predict the development of iron depletion, hemoglobin deferral, and/or

iron deficient hemoglobin deferral in active whole blood and double red cell donors at subsequent blood donations. The data collected will help evaluate hemoglobin distributions in the blood donor population (eligible and deferred donors) and compare them with NHANES data. Other secondary objectives include elucidating key genetic influences on hemoglobin levels and iron status in a donor population as a function of donation history; and establishing a serum and DNA archive to evaluate the potential utility of future iron studies and genetic polymorphisms.

This study will develop better predictive models for iron depletion and hemoglobin deferral (with or without iron deficiency) in blood donors; allow for the development of improved donor screening strategies and open the possibility for customized donation frequency guidelines for individuals or classes of donors; provide important baseline information for the design of targeted iron supplementation strategies in blood donors, and improved counseling messages to blood donors regarding diet or supplements; and by elucidating the effect of genetic iron protein polymorphisms on the development of iron depletion, enhance the understanding of the role of these proteins in states of iron stress, using frequent blood donation as a model.

*Frequency of Response:* Twice.

*Affected Public:* Individuals.

*Type of Respondents:* Adult blood donors.

*The annual reporting burden is as follows:*

*Estimated Number of Respondents:*

*Baseline Visit:* 3,750.

*Follow-up Visit:* 1720.

*Estimated Number of Responses per Respondent:* 1.

*Average Burden of Hours per Response:*

*Baseline Visit:* 0.12.

*Follow-up Visit:* 0.1.

*Estimated Total Annual Burden*

*Hours Requested:*

*Baseline Visit:* 450.

*Follow-up Visit:* 172.

*The annualized cost to respondents is estimated at:*

*Baseline Visit:* \$8,100.

*Follow-up Visit:* \$3,096 (based on \$18 per hour).

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.