



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL)

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), 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.

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.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: 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. Larissa Aviles-Santa, 6701 Rockledge, Epidemiology Branch, Program in Prevention and Population Sciences, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr, MSC 7936, Bethesda, MD 20892-7936, or call non-toll-free number 301-435-0450, or E-mail your request, including your address to avilessantal@nhlbi.nih.gov . Formal requests for additional plans and instruments must be requested in writing.

COMMENT 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.

PROPOSED COLLECTION: The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL), -Revised, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to study the prevalence of cardiovascular and pulmonary disease and other chronic diseases, and their risk and protective factors, understand their relationship to all-cause, cardiovascular and pulmonary morbidity and mortality, and understand the role of sociocultural factors (including acculturation) on the prevalence or onset of disease among over 16,400 Hispanics/Latinos of diverse origins, aged 18-74

years at enrollment, living in four U.S. communities: San Diego, California; Chicago, Illinois; Miami, Florida, and the Bronx, New York. In order to achieve these objectives, the HCHS/SOL had two integrated components:

1. Examination of the cohort following a standardized protocol, which consisted of interviews and clinical measurements to assess physiological and biochemical measurements including DNA/RNA extraction for ancillary genetic research studies.

2. Follow-up of the cohort, which consists of an annual telephone interview to assess vital status, changes in health status and medication intake, and new cardiovascular and pulmonary events (including fatal and non-fatal myocardial infarction and heart failure; fatal and non-fatal stroke; and exacerbation of asthma and chronic obstructive pulmonary disease).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 30,940.

Estimated Annualized Burden Hours

Type of Respondents	Survey Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Burden Hours
Participants Visit 2 Examination (Appendix 15)	Pre-visit scheduling & safety screening	13,878	1	2/60	463
	Reception, informed consent, medical releases	13,878	1	20/60	4,626
	Ppt. safety update and routing	13,878	1	2/60	463
	Change clothes, urine specimen	13,878	1	10/60	2,313
	Updated personal information	13,878	1	5/60	1,157
	Anthropometry	13,878	1	7/60	1,619
	Determination of fasting & blood draw	13,878	1	11/60	2,544
	Determination of blood glucose, OGTT	13,878	1	6/60	1,388
	Seated BP	13,878	1	9/60	2,082
	Echocardiography	8,000	1	30/60	4,000
	2-hour blood draw, snack	13,878	1	12/60	2,776
	Personal Medical History	13,878	1	10/60	2,313
	Reproductive Medical History	9,000	1	9/60	1,350
	Pregnancy Complications History	9,000	1	4/60	600
	Socio-economic Status – Occupation	13,878	1	3/60	694
	Health Care Access and Utilization	13,878	1	15/60	3,470
	Chronic Stress	13,878	1	4/60	925
	Family Cohesion	13,878	1	5/60	1,157
	Social Support	13,878	1	3/60	694
	Acculturation	13,878	1	3/60	694
	Well Being	13,878	1	4/60	463
Abbreviated Medication Use	13,878	1	4/60	925	
Tobacco Use	13,878	1	4/60	925	
Alcohol Use	13,878	1	3/60	694	
Participant Feedback	13,878	1	12/60	2,776	
	Total			197/60	41,111
Participants Annual Follow-Up Interview (Appendix 16)	AFU Year 3	3,146	1	15/60	787
	AFU Year 4	9,033	1	15/60	2,258
	AFU Year 5	14,259	1	15/60	3,565
	AFU Year 6	16,222	1	15/60	4,055
	AFU Year 7	16,222	1	15/60	4,055
	AFU Year 8	16,222	1	15/60	4,055
	AFU Year 9	16,222	1	15/60	4,055
	AFU Year 10	16,222	1	15/60	4,055
	AFU Year 11	16,222	1	15/60	4,055
		Total			120/60

Dated: March 11, 2014.

Michael Lauer,
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Lynn Susulske,
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