TABLE 3.—Continued

Item No.	Title of Standard	Reference No. and Date
222	Sterilization of Health Care Products—Biological and Chemical Indicators—Test Equipment	ANSI/AAMI/ISO 18472:2006
223	Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	ANSI/AAMI/ISO 11138–1:2006
224	Sterilization of Health Care Products—Radiation—Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	ANSI/AAMI/ISO 11137–1:2006
225	Sterilization of Health Care Products—Radiation—Part 2: Establishing the Sterilization Dose	ANSI/AAMI/ISO 11137–2:2006
226	Sterilization of Health Care Products—Radiation—Part 3: Guidance on Dosimetric Aspects	ANSI/AAMI/ISO 11137–3:2006
H. Tissue Engineering		
9	Standard Guide for Classification of Therapeutic Skin Substitutes	ASTM F2311–06
10	Standard Guide for *in vivo* Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage	ASTM F2451–05

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Web site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (See **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 018'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 018. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 30, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–18021 Filed 9–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 11, 2007, pages 37789–37790, and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may

not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL).

Type of Information Collection Request: New Collection. *Need and Use of Information Collection:* The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL) will identify risk factors for cardiovascular and lung disease in Hispanic populations and determine the role of acculturation in the prevalence and development of these diseases. Hispanics, now the largest minority population in the US, are influenced by factors associated with immigration from different cultural settings and environments, including changes in diet, activity, community support, working conditions, and health care access. This project is a multicenter, six-and-a-half year epidemiologic study and will recruit 16,000 Hispanic men and women aged 18–74 in four community-based cohorts in Chicago, Miami, San Diego, and the Bronx. The study will also examine measures of obesity, physical activity, nutritional habits, diabetes, lung and sleep function, cognitive function, hearing, and dental conditions. Closely integrated with the research component will be a community and professional education component, with the goals of bringing the research results back to the community, improving recognition and control of risk factors, and attracting and training Hispanic researchers in epidemiology and population-based research.

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; physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 39,844; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 1.1; and *Estimated Total Annual Burden Hours Requested:* 44,688. The annualized cost to respondents is estimated at $149,415, assuming respondents time at the rate of $15 per hour and physician time at the rate of $55 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE A.12.1.—ESTIMATE OF RESPONDENT BURDEN HCHS/SOL

Type of response	Number of respondents	Number of responses	Time per response (hours)	Burden (hours)
a. Recruitment contacts	22,369	1	0.08	1,790
b. Household enumeration	4,191	1	0.17	712
c. Telephone contact to set up appointment	6,667	1	0.08	533
d. Appointment Confirmation	6,667	1	0.08	533
e. CLINIC EXAM:				
e1. Procedures	5,333	1	3.67	19,572
e2. Questionnaires	5,333	1	2.75	14,666
f. Participant Telephone Interviews:				
24-hour Dietary Intake Recall	5,333	1	0.67	3,573
Follow-Up Call	5,333	1	0.50	2,667
Total, Participant	38,560			44,046
Non-participant components: [1]				
a. Physician, hospital and nursing home contacts for outcomes ascertainment (total = 1,254):				
Deaths	60	1	0.50	627
CHF	90			
Stroke	132			
CHD	650			
COPD	210			
Asthma	112			
b. Informant contact	30	1	0.50	15
Total, Participant and Non-Participant Components	39,844			44,688

[1] Annual burden is place on physicians and health care providers and respondent relatives/informants through request for information which will help in the compilation of the number and nature of new fatal and non-fatal events.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Larissa Aviles-Santa, Deputy Project Officer, NIH, NHLBI, 6701 Rockledge

Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll-free number 301–435–1284 or E-mail your request, including your address to: *AvilessantaL@NHLBI.NIH.GOV.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: September 7, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: September 7, 2007.

Suzanne Freeman,

Chief, FOIA, NHLBI, National Institutes of Health.

[FR Doc. E7–17986 Filed 9–11–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Cardiovascular Health Study (CHS)

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 Cardiovascular Health Study. *Type of Information Request:* Reinstatement. (OMB No. 0925–0334). *Need and Use of Information Collection:* This study quantifies associations between conventional and hypothetical risk factors and coronary heart disease (CHD) and stroke in people age 65 years and older. The primary objectives include quantifying associations of risk factors with subclinical disease; characterizing the natural history of CHD and stroke; and identifying factors associated with clinical course. The findings provide important information on cardiovascular disease in an older U.S. population and lead to early treatment of risk factors associated with disease and identification of factors that may be important in disease prevention. OBM clearance is being sought for data collection activities at only one of the four CHS field centers (the Pittsburgh field center), which are expected to end on May 31, 2008. Other data collection efforts in the CHS cohort are supported by various non-contract funding sources. *Frequency of response:* twice a year (participants) or once per cardiovascular disease event (proxies and physicians); *Affected public:* Individuals. *Types of Respondents:* Individuals recruited for CHS and their selected proxies and physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 556; *Estimated Number of Responses per respondent:* 1.2; *and Estimated Total Annual Burden Hours Requested:* 289. The annualized cost to respondents is estimated at: $14,450.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent*	Average burden hours per response	Estimated total annual burden hours requested
Participants	346	1.2	0.5	208
Physicians	70	1.2	0.1	8
Participant proxies	121	1.2	0.5	73
Total	537	1.2	0.45	289

*Total for 3 years.

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 will have practical utility; (2) The accuracy of the agency's estimate of 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 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 data collection plans and instruments, contact Dr. Jean Olson, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD 20892–7936, or call 301–435–0397 (non-toll-free number), or e-mail your request, including your address to: *OlsonJ@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 29, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Suzanne Freeman,

Chief, FOIA, NHLBI, National Institutes of Health.

[FR Doc. E7–18012 Filed 9–11–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the