

input from the Committee. The SAB will then discuss the research direction and provide advice on the state of the science, future research directions, and impact of the findings on the public health.

Following an open discussion of all the information presented, the open session of the meeting will close so that the SAB members can discuss personnel issues at NCTR.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** On November 8, 2011, from 8:15 a.m. to 4:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 28, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 20, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 21, 2011.

**Closed Committee Deliberations:** On November 9, 2011, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Margaret Miller at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 11, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-26891 Filed 10-17-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery**

**AGENCY:** National Institutes of Health, National Institute on Drug Abuse (NIDA), HHS.

**ACTION:** 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

**SUMMARY:** As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, NIDA has submitted a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

**DATES:** Comments must be submitted within 30 days after publication in FR.

**ADDRESSES:** Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, *Attn:* NIH Desk Officer, by E-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov), or by fax to 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Genevieve deAlmeida-Morris, Health Research Evaluator, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Boulevard, Bethesda, MD 20892-9557, or call non-toll-free number (301) 594-6802 or E-mail your request, including your address to [dealmeig@nida.nih.gov](mailto:dealmeig@nida.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

**Title:** Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**Abstract:** The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be

eligible for submission for other generic mechanisms that are designed to yield quantitative results.

No comments were received in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide NIDA's projected average estimates for the next three years:<sup>1</sup>

*Current Actions:* New collection of information.

*Type of Review:* New Collection.

*Affected Public:* Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

*Average Expected Annual Number of activities:* 4.

*Respondents:* 740.

*Annual responses:* 740.

*Frequency of Response:* Once per request.

*Average minutes per response:* 50.

*Burden hours:* 516.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: October 6, 2011.

**Mary Affeldt,**

*Executive Officer (OM Director), NIDA.*

[FR Doc. 2011-26906 Filed 10-17-11; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 9, 2011, pages 48872-48873, and allowed 60 days for public comment. Two public comments were received. One comment questioned why government resources are being devoted to studying the health of Hispanic groups. The comment was acknowledged by NHLBI. The second comment, from an advocacy group, inquired about exploring the availability of paid sick leave and its relationship to Hispanic health. NHLBI acknowledged and followed-up on this comment.

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:* Revision of currently approved collection (OMB# 0925-0584). *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 U.S., 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 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: 17,284; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.3072; and *Estimated Total Annual Burden Hours Requested:* 5,309. The annualized cost to respondents is estimated at \$104,718, 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.

#### ESTIMATE OF RESPONDENT BURDEN [HCHS/SOL]

| Type of respondents                       | Number of respondents | Frequency of response | Average time per response | Annual hour burden |
|-------------------------------------------|-----------------------|-----------------------|---------------------------|--------------------|
| <i>Participant Telephone Interviews</i>   |                       |                       |                           |                    |
| a. Follow-Up Call, Year 1 .....           | 1,333                 | 1                     | 0.75                      | 1,000              |
| b. Follow-Up Call, Year 2 .....           | 5,333                 | 1                     | 0.25                      | 1,333              |
| c. Follow-Up Call, Years 3, 4, 5, 6 ..... | 9,334                 | 1                     | 0.25                      | 2,334              |
| Subtotal .....                            |                       |                       |                           | 4,667              |

<sup>1</sup> The 60-day notice included the following estimate of the aggregate burden hours for this generic clearance federal-wide:

*Average Expected Annual Number of activities:* 25,000.

*Average number of Respondents per Activity:* 200.

*Annual responses:* 5,000,000.

*Frequency of Response:* Once per request.

*Average minutes per response:* 12.

*Burden hours:* 2,500,000.