alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov*.

Dated: September 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22658 Filed 9–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Process Evaluation of the Early Independence Award (EIA) Program

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Strategic Coordination (OSC), Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 13, 2012 (Vol. 77, No 114, Page 35408), and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH 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: Process Evaluation of the Early Independence Award (EIA) Program. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will assess the EIA program operations. The primary objectives of the study are to: (1) Assess if the Requests for Applications (RFAs) are meeting the needs of applicants; (2) document the selection process; (3) document EIA program operations; (4) assess the progress being made by the Early Independence Principal Investigators; and (5) assess the support provided by the Host Institutions to the Early Independence Principal Investigators. The findings will provide valuable information concerning: (1) Aspects of the program that could be revised or improved; (2) progress made by the Early Independence Principal Investigators; and (3) implementation of the program at Host Institutions. *Frequency of Response:* On occasion. *Affected Public:* None. *Type of Respondents:* Applicants, reviewers, and awardees. The annual reporting burden is as follows: *Estimated Number of Respondents:* 390; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .4; and *Estimated Total Annual Burden Hours Requested:* 158. The annualized cost to respondents is estimated at $9,774. There are no Capital Costs to report.

A.12.1—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hrs.)	Annual hour burden
Editorial Board Reviewers (paper survey)	15	1	15/60	4
Applicants—Junior Scientists (online survey)	150	1	15/60	38
Applicants—Officials of Host Institutions (online survey)	150	1	15/60	38
Awardees—Early Independence Principal Investigator (paper survey—beginning of 1st year of award)	12	1	30/60	6
Awardees—Early Independence Principal Investigator (phone interview—end of 1st year of award)	12	1	1	12
Awardees—Early Independence Principal Investigator (online survey—end of 2nd and 3rd year of award)	24	1	1	24
Awardees—Point of Contact at Host Institution (phone interview—end of 1st year of award)	12	1	1	12
Awardees—Point of Contact at Host Institution (online survey—end of 2nd and 3rd year of award)	24	1	1	24
Total				158

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.

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. Ravi Basavappa, OSC, DPCPSI, Office of the Director, NIH, 1 Center Drive, MSC 0189, Building 1, Room 203, Bethesda, MD 20892–0189; telephone 301–594–8190; fax 301–435–7268; or email your request, including your address, to *earlyindependence@mail.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, 2012.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2012–22741 Filed 9–13–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 24, 2012 (77 FR 11136) and allowed 60 days for public comment. There was one public comment that was not relevant to the scope, methodology, or burden of the study. The program staff submitted a response to the public 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: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI) (OMB No. 0925–0654). *Type of Information Collection Request:* Extension. *Need and Use of Information Collection:* Incidence rates of certain lymphomas have increased in the United States and in many other parts of the world. The contribution of environmental, occupational, and genetic factors to the cause of lymphoma has generated a series of new findings from epidemiological studies conducted in the United States that have attempted to explain this increase. This study focuses on collecting critically needed information to understand and reduce the cancer burden from lymphoid malignancies in the Asian population, the incidence of which has risen in recent decades. Specifically, environmental exposures to industrial emissions, genetic susceptibility, viral exposures, early life exposures, ultraviolet (UV) radiation exposures, and other risk factors for lymphoma overall and specifically for populations in Asia will be examined. Patients from 19 participating hospitals will continue to be screened and enrolled. There will be a one-time computer-administered interview, and patients will also be asked to provide a one-time blood and buccal cell mouth wash sample and lymphoma cases will be asked to make available a portion of their pathology sample. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Newly diagnosed patients with lymphoma or patients undergoing surgery or other treatment for non-cancer related medical issues who live in Taiwan and in Hong Kong, Chengdu and Tianjin, China will be enrolled at treating hospitals. The annual reporting burden is estimated at 5,302 hours (see Table below). There are $77,000 in Capital Costs, Operating Costs, and/or Maintenance Costs to report.

ESTIMATES OF ANNUAL BURDEN HOURS

Category of respondents	Types of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Individuals	Patients to be Screened	3,100	1	5/60	258
	Patients with Lymphoma	1,100	1	105/60	1,925
	Other Patients	1,100	1	105/60	1,925
	Study Pathologists	19	58	5/60	92
	Interviewers	19	116	30/60	1102
Total					5,302

Request For Comments: 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 proposed performance of the functions of the agency, including whether the information may have practical utility; (2) The accuracy of the 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.

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 Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans, contact Nathaniel Rothman, Senior Investigator for the Occupational and Environmental Epidemiology Branch, Division of Epidemiology and Genetics, National Cancer Institute, 6120 Executive Boulevard, Room 8118, Rockville, MD 20892 or call non-toll-free number 301–496–9093 or email your request, including your address to: *rothmann@mail.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.