create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0701.

The guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and 21 CFR part 803. These regulations contain collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, 0910–0437, and 0910–0543. In addition, the guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa–1), which include collections of information approved under OMB control numbers 0910–0636 and 0910–0635.

IV. Electronic Access

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

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4288 Filed 2–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: STAR METRICS (Science and Technology for America's Reinvestment: Measuring the EffecTs of Research on Innovation, Competitiveness and Science)

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, 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 Oct 5, 2011 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 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: STAR METRICS (Science and Technology for America's Reinvestment: Measuring the EffecTs of Research on Innovation, Competitiveness and Science). *Type of Information Collection Request:* Extension of OMB number 0925–0616, expiration date 03/31/2012. *Need and Use of Information Collection:* The aim of STAR METRICS is twofold. The goal of STAR METRICS is to continue to provide mechanisms that will allow participating universities and Federal agencies with a reliable and consistent means to account for the number of scientists and staff that are on research institution payrolls, supported by federal funds. In subsequent generations of the program, it is hoped that STAR METRICS will allow for measurement of science impact on economic outcomes (such as job creatfon), on knowledge generation (such as citations, and patents) as well as on social and health outcomes.

Frequency of Response: Quarterly.~

Affected Public: Universities and other research institutions.

Type of Respondents: University administrators.

The annual reporting burden is as follows:

Estimated Number of Respondent: 100.

Estimated Number of Responses per Respondent: 4.

Average Burden Hours per Response: 2.5.

Estimated Total Annual Burden Hours Requested: 1,315.

The annualized cost to respondents is estimated to be $65,750. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Stage I: One time data input	7	1	45	315
Stage 2: Ongoing quarterly data input	100	4	2.5	1,000
Total				1,315

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 functioning of the National Cancer Institute, 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.

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 and instruments, contact: George Chacko, Office of Planning, Analysis, and Evaluation, Center for Scientific Review, 6701 Rockledge Drive, Suite 3030, Bethesda, MD 20892 or call non-toll-free at 301–435–1111 or email your request, including your address to: *chackoge@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.

George Chacko,

Director, Office of Planning, Analysis, and Evaluation, Center for Scientific Review, National Institutes of Health.

[FR Doc. 2012–4271 Filed 2–23–12; 8:45 am]

BILLING CODE 4104–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; a Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

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 Cancer Institute (NCI), 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: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI). *Type of Information Collection Request:* Emergency. *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 novel findings from epidemiological studies conducted in the United States that have attempted to explain this increase. However, none of the chemical associations have been conclusively established and the identification of the key, functional alleles in gene regions associated with risk of NHL requires further elucidation. Further, the ability to follow-up, confirm, and extend these observations in the United States is limited by the low prevalence and limited range of several important chemical and viral exposures and the high to complete linkage disequilibrium among key candidate genetic loci in Western populations. To optimize the ability to build on and clarify these findings, it is necessary to investigate populations that differ from those in the West in both exposure patterns and underlying genetic structure. A multidisciplinary case-control study of lymphoma in Asia, where lymphoma rates have also risen, provides an opportunity to replicate and extend recent and novel observations made in studies in the West in a population that is distinctly different with regard to patterns of key risk factors, including range of exposures, prevalence of exposures, correlations between exposures, and variation in gene regions of particular interest. It will also improve the ability to understand the causes of certain types of rare lymphoma tumors in the United States that occur at much higher rates in Asia. As such, AsiaLymph will confirm and extend previous findings and yield novel insights into the causes of lymphoma in both Asia and in the United States. The major postulated risk factors for evaluation in this study are chemical exposures (i.e., organochlorines, trichloroethylene, and benzene) and genetic susceptibility. Other factors potentially related to lymphoma, such as viral infections, ultraviolet radiation exposure, medical conditions, and other lifestyle factors will also be studied. Patients from 19 participating hospitals will 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	1,102
Total					5,302