simulation modeling of the U.S. blood supply, including the possible application of an FDA computer simulation model of the U.S. blood supply in support of emergency preparedness and planning for potential disruptions in blood donations; (2) discuss with the blood community the utility of simulation methods as a complementary approach to support planning for daily inventory needs and forecasting for future blood donations and demand; (3) discuss the capabilities and limitations of the U.S. computer simulation model, assumptions used in the model and data gaps for model validation; (4) describe and prioritize future model enhancements to extend the model predictions from red blood cell units to other blood components, such as plasma and platelets; and (5) discuss the level of detail required for a model to characterize the U.S. blood supply and to develop possible scenarios in which shortages may be addressed through countermeasures such as the use of local and interregional transfers of blood and blood components.

*Transcripts:* Transcripts of the public workshop may be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.*

Dated: May 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–12593 Filed 5–23–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; Web-Based Assessment of the Clinical Studies Support Center (CSSC)

*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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 12, 2011, Volume 77 No. 44, pages 14531–14533 and allowed 60-days for public comment. One comment was 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 current valid OMB control number.

*Proposed Collection: Title:* Web-Based Assessment of the Clinical Studies Support Center (CSSC). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* Over the past decade Data Safety Monitoring Boards (DSMBs), Observational Safety Monitoring Boards (OSMBs), and Protocol Review Committees (PRCs) have become an important quality standard in clinical trials and research involving human subjects. The National Heart, Lung, and Blood Institute (NHLBI) alone currently has approximately 60 active review Committees. These include DSMBs, OSMBs, and PRCs which are independent groups convened to review study protocols developed under NHLBI funded Clinical Trial Networks. These committees are composed of members with expertise in biostatistics, clinical trials, bioethics, and other specific scientific and research areas. The NHLBI is charged with ensuring the highest quality of each Institute-funded clinical research project and compliance with Department of Health and Human Services (DHHS)/National Institutes of Health (NIH)/NHLBI regulations regarding human subject protections and safety monitoring. To carry out this responsibility, the NHLBI program staff instituted a new methodology for supporting the administration of NHLBI-appointed Committees in 2009. The new methodology included the establishment of the Clinical Studies Support Center (CSSC) under the direction of Westat, Inc. The CSSC is a pilot program to support the operations of NHLBI's DSMBs, Observational OSMBs, and PRCs for the Division of Blood Diseases and Resources. Utilizing Executive Secretaries to support each NHLBI safety monitoring board, the CSSC is responsible for documenting standardized operating procedures related to the administration of monitoring committees and the support center in a CSSC Manual of Operations and Procedures (MOP); coordinating meeting space and logistics for in-person meetings, Web conferences, and teleconferences; managing distribution of adverse event notifications to DSMB chairs and members, new protocols, and proposed amendments; and providing Executive Secretaries who provide scientific and administrative support to document board recommendations related to the safety and efficacy of trial interventions and the quality and completeness of clinical research study data. To move forward with full knowledge of current Committee operations and to monitor the effect of newly established procedures, Westat is required, as part of this contract, to conduct an assessment of the efficiency and effectiveness of NHLBI CSSC committee operations. As part of this assessment, the NHLBI requires feedback and advice regarding the support provided by the CSSC for monitoring board operations. To this end, a Web-based questionnaire will be administered to Chairs and members of monitoring boards to learn about their opinions about specific CSSC activities and their satisfaction with the performance of CSSC staff.

*Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Monitoring board members. The annual reporting burden is a follows: *Estimated Number of Respondents:* 90; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33 and *Estimated Total Annual Burden Hours Requested:* 30.36. The annualized cost to respondents is estimated at: $ 3.036 (based on $100 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Table A.12.1. ESTIMATES OF HOUR BURDEN**

| Type of respondents | Number of respondents | Frequency of responses | Average time per response | Annual hour burden |
|---|---|---|---|---|
| D/OSMB Chairs | 10 | 1 | 0.33 | 3.3 |
| D/OSMB Members | 78 | 1 | 0.33 | 25.74 |

| Type of respondents | Number of respondents | Frequency of responses | Average time per response | Annual hour burden |
|---|---|---|---|---|
| Members in two D/OSMB | 2 | 2 | 0.33 | 1.32 |
| Total | 90 | | | 30.36 |

TABLE 1–1 AND 1–2—ESTIMATE OF REQUESTED BURDEN HOURS AND DOLLAR VALUE OF BURDEN HOURS

| Type of respondents | Number of respondents | Frequency of response | Average time per response | Hourly age rate | Respondent cost |
|---|---|---|---|---|---|
| **Table A.12–2. ANNUALIZED COST TO RESPONDENTS** | | | | | |
| DSMB Chairs | 10 | 1 | .33 | 100 | 330 |
| DSMB Members | 78 | 1 | .33 | 100 | 2,574 |
| Members in two D/OSMB | 2 | 2 | .33 | 100 | 132 |
| Totals | 90 | | | | 3,036 |

*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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, 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: Erin Smith, Contracting Officer Technical Representative, Room 9149, 6701 Rockledge Drive, Bethesda, MD 20892–7950, or call 301–435–0050, or Email your request to *smithee@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: May 1, 2012.

**Keith Hoots,**

*Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH.*

Dated: May 14, 2012.

**Lynn Susulske,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

[FR Doc. 2012–12656 Filed 5–23–12; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request; Collection of Customer Service, Demographic, and Smoking/Tobacco Use Information From the National Cancer Institute's Cancer Information Service (CIS) Clients (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:* Collection of Customer Service, Demographic, and Smoking/Tobacco Use Information from the National Cancer Institute's Cancer Information Service (CIS) Clients (NCI). *Type of Information Collection Request:* Revision of currently approved collection 0925–0208 (expiration 08/30/2012). *Need and Use of Information Collection:* The National Cancer Institute's Cancer Information Service (CIS) provides the latest information on cancer, clinical trials, and tobacco cessation in English and Spanish. Clients are served by calling 1–800–4–CANCER for cancer information; 1–877–44U–QUIT for smoking cessations services; using the NCI's LiveHelp, a web-based chat service; using NCI's Contact Us page on *www.cancer.gov*; and using NCI's Facebook page. CIS currently conducts a brief survey of a sample of telephone and LiveHelp clients at the end of usual service—a survey that includes three customer service and twelve demographic questions (age, sex, race, ethnicity, education, household income, number in household, and five questions about health care/coverage). Characterizing clients and how they found out about the CIS is essential to customer service, program planning, and promotion. The NCI also conducts a survey of individuals using the CIS's smoking cessation services—a survey that includes 20 smoking/tobacco use ''intake'' questions that serve as a needs assessment that addresses smoking history, previous quit attempts, and motivations to quit smoking. An additional question is used with callers who want to receive proactive call-back services. Responses to these questions enable Information Specialists to provide effective individualized counseling. The NCI's CIS also responds to cancer-related inquiries to its Facebook page and its Contact Us form on *www.cancer.gov* but does not collect customer service or demographic questions on these access channels. *Frequency of Response:* Once. *Affected Public:* Individuals or households. *Type of Respondents:* People with cancer; their relatives and friends; and general public, including smokers/tobacco users. Annualized estimates for numbers of respondents and respondent burden are presented in Table 1.