people, caregivers, and health professionals (physicians and non-physicians). The annual reporting burden is as follows: *Estimated Number of Respondents:* 630. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* 0.37. *Estimated Total Annual Burden Hours Requested:* 234. The annualized cost to respondents is estimated at: $5,680. There are no Capital Costs to report. There are no 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
Older adults	260	1	.37	97
Non-physician health professionals and caregivers	310	1	.35	107
Physicians	60	1	.5	30
Total				234

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: Megan Homer, Writer/Editor, Office of Communications and Public Liaison, NIH, Building 31C Room 5C27, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–496–1752 or E-mail your request, including your address to: *homerm@mail.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: September 22, 2010.

Lynn Hellinger,

Director of Management, National Institutes of Health.

[FR Doc. 2010–24277 Filed 9–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors: Improving the Safety of the U.S. Blood Supply Through Hemovigilance

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 the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the U.S. blood supply through hemovigilance. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Information on current risk factors in blood donors as assessed using analytical study designs is largely unavailable in the U.S. Studies of risk factor profiles among HIV-infected donors were funded by the CDC for approximately 10 years after implementation of serologic screening in the mid-1980s, whereas studies of HTLV- and HCV-seropositive (and indeterminate) donors, funded by NIH, were conducted in the early 1990s, but unfortunately, none of these studies is ongoing. Infection trend analyses have been conducted by the American Red Cross (ARC). The findings show continued HIV risk with the prevalence of HIV in first time donors hovering around 10 per 100,000 donations in each of the last 10 years and the incidence in repeat donors increasing from 1.49 per 100,000 person-years in 1999–2000 to 2.16 per 100,000 persons-years in 2007–2008. While the prevalence of HCV in first time donors decreased over this time interval from 345 to 163 per 100,000 donations, the incidence in repeat donors did not decrease and evidence of incident infection in first time donors increased. Moreover specific age, gender and race/ethnicity groups were over-represented. Significantly increased incidence of both HIV and HCV were observed in 2007/2008 compared to 2005/2006. Similar analyses for HBV have shown an incidence in all donors of 3.4 per 100,000 person-years which is lower than earlier estimates, but remains higher than for HIV and HCV.

This project represents a collaborative pilot research study that will include a comprehensive interview study of viral infection positive blood donors at the American Red Cross (ARC), Blood Systems Inc. (BSI) and New York Blood Center (NYBC) in order to identify the current predominant risk factors for virus positive donations and will also establish a donor biovigilance capacity that currently does not exist in the U.S. At this time it is not easy to integrate risk factor data and disease marker surveillance information within or across different blood collection organizations because common interview procedures and laboratory confirmation procedures are not being used and so we cannot easily tabulate and analyze behavioral risks or viral infections in U.S. blood donors. This creates the potential for gaps in our understanding of absolute incidence and prevalence as well as risks that could lead to transfusion-transmitted disease. Combined data are critical for appropriate national surveillance efforts. For example, this information could be used to target educational interventions to reduce donations from persons with high risk behaviors. This is particularly important in the case of

behaviors associated with incident (recently acquired) infections because these donations have the greatest potential transmission risk because they could be missed during routine testing. As part of the project a comprehensive research-quality biovigilance database will be created that integrates existing operational information on blood donors, disease marker testing and blood components collected by participating organizations into a research database. The combined database will capture infectious disease and risk factor information on nearly 60% of all blood donors and donations in the country. Following successful completion of the risk factor interviews and research database development, the biovigilance network pilot can be expanded to include additional blood centers and/or re-focused on other safety threats as warranted, such as XMRV. This pilot biovigilance network will thereby establish a standardized process for integration of information across blood collection organizations.

The Specific Aims are to:

(1) Define consensus infectious disease testing classification algorithms for HIV, HCV, HBV, and HTLV that can be used to consistently classify donation testing results across blood collection organizations in the U.S. This will allow for better estimates of infection disease marker prevalence and incidence in the U.S.

(2) Determine current behavioral risk factors associated with prevalent and incident (when possible) HIV, HCV, HBV and HTLV infections in blood donors, including parenteral and sexual risks, across the participating blood collection organizations using a case-control study design.

(3) Determine nationally-representative infectious disease marker prevalence and incidence for HIV, HCV, HBV, and HTLV overall and by demographic characteristics of donors. This will be accomplished by forming research databases from operational data at BSI and NYBC into formats that can be combined with the ARC research database.

(4) Analyze integrated risk factor and infectious marker testing data together because when taken together these may show that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult blood donors. The annual reporting burden is a follows: *Estimated Number of Respondents:* 4150; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.58 and *Estimated Total Annual Burden Hours Requested:* 2407. The annualized cost to respondents is estimated at: $43,326 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Tables 1–1 and 1–2: Estimate of Requested Burden Hours and Dollar Value of Burden Hours

TABLE 1–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Cases	1650	1	0.58	957
Controls	2500	1	0.58	1450
Total	4150			2407

TABLE 1–2—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Average time per response	Hourly wage rate	Respondent cost
Cases	1650	1	0.58	$18	17,226
Controls	2500	1	0.58	18	26,100
Total	4150				43,326

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 Ms Elizabeth Wagner, Project Officer, NHLBI, Two Rockledge Center, Room 9030, 6701 Rockledge Drive, Bethesda, MD 20892–7950, or call 301–451–9491, or E-mail your request to *elizabeth.wagner@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: September 16, 2010.

Ms. Elizabeth Wagner,

NHLBI Project Officer, NHLBI, National Institutes of Health.

[FR Doc. 2010–24278 Filed 9–27–10; 8:45 am]

BILLING CODE 4140–01–P