DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request; National Donor Research and Education Study-II

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

PROPOSED COLLECTION: *Title:* National Donor Research and Education Study-II. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study is the second large anonymous mail survey to be sent to a random sample of blood donors at five blood centers participating in the Retrovirus Epidemiology Donor Study (REDS). In addition to the REDS blood centers, this survey will also be sent to a sample of donors in selected non-REDS regions that utilize a variety of donor incentives. Study results will provide data for monitoring the safety of the U.S. blood supply, and will facilitate the development, evaluation and refinement of educational, recruitment and qualification strategies for U.S. blood donors. The proposed new study will update and extend the unique findings obtained in the first blood donor survey so as to minimize the likelihood that donors with risk factors for transfusion-transmitted diseases will enter the blood donor pool. There is a strong likelihood that, like the first survey effort, the resulting findings will be directly applied to blood banking operational practice. the new survey is specifically designed to obtain data on the prevalence and impact of donor incentives on donor retention and blood safety. The FDA has identified this as a priority area for investigation. Other specific objectives of this survey are to: (1) Evaluate donor understanding and acceptance, and the safety impact of newly-changed laboratory and donor screening procedures that have been implemented since the previous donor survey study (e.g., removal of the confidential unit exclusion ''CUE'' process at two REDS sites; additional questions about Creutzfeldt-Jakob and parasitic diseases; and addition of HIV p24 antigen testing); (2) Estimate the efficacy, safety impact and donor acceptance of new donor screening procedures that are anticipated to occur within the next 12-24 months (e.g., improved CUE procedures, implementation of computer-assisted donor screening); (3) Provide ''pre-'' (baseline) and ''post-'' (evaluation) measures for new donor qualification procedures expected to occur operationally at blood centers within the time period of study including: deferral for intranasal cocaine use in the past year; modification of the time period for sexual risk deferrals from ''since 1977'' to within the past 12 (or 24) months; clarification of wording regarding sexual contact with ''at risk'' individuals; and addition of questions about donating primarily for the purpose of receiving the test results for the AIDS virus; (4) Assess changes in the prevalence and characteristics of donors who report donating for therapeutic reasons (e.g., those with iron storage disease), and donors who report donating primarily to receive test results for the AIDS virus as a result of the March 1996 implementation of HIV p24 antigen testing; (5) Determine the extent to which active donors with reactive tests for anti- HBc and syphilis have increased levels of behavioral risks that should have resulted in deferral; (6) Measure the extent to which seropositivity for current syphilis screening tests predicts a recent history of diagnosed syphilis; and (7) Measure blood donor knowledge of infectious disease risks and the behavioral factors that should defer them from donating, to identify weaknesses in the current donor educational process. *Frequency of Response:* One-time data collection. *Affected Public:* Individuals.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per responses	Estimated total annual burden hours requested
Blood Donors	77,000	1	.3333	25,664

The annualized cost to respondents is estimated at: $256,641 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 function of the agency, 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.

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. George J. Nemo, Group Leader, Transfusion Medicine, Scientific Research Group, Division of Blood Diseases and Resources, NHLBI, NIH, Two Rockledge Centre, Suite 10042, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call non-toll free number (301) 435–0075 or e-mail your request, including your address to: nemog@gwgate.nhlbi.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before July 7, 1997.

Dated: April 25, 1997.

Sheila E. Merritt,

Executive Officer, NHLBI.

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