

has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

Dated: October 21, 1996.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[FR Doc. 96-27344 Filed 10-23-96; 8:45 am]

BILLING CODE 4160-15-P

**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 stage 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 monitoring the safety of the U.S. blood supply, study results 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 participate in 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. 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-Jacob and parasitic diseases; addition of HIV p24 antigen testing; increased use of donation incentives); (2) Pilot test new donor screening procedures that are anticipated to occur within the next 12-24 months in order to estimate their efficacy, safety impact and donor acceptance (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 tests 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; (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; and (8) Assess the attitudes of donors regarding establishment of stored frozen repositories from their donations, use of these samples for future research testing designed to improve transfusion safety, and the adequacy of different levels of informed consent. *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 .....	38,500	1	.3333	12,832

The annualized cost to respondents is estimated at: \$128,320 (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 technical collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION:** 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 December 23, 1996.

Dated: October 17, 1996.

Shelia E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96-27327 Filed 10-23-96; 8:45 am]

BILLING CODE 4140-01-M

**National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request—Evaluation of the NHLBI Short-Term Training for Minority Students Program**

**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:* Evaluation of the NHLBI Short-Term Training for Minority Students Program. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* When the short-term training program was implemented, applicants were provided broad guidance that enabled them to structure their program in the manner they deemed most likely to accomplish the program objectives. The proposed evaluation will assess the effectiveness of the short-term training program in meeting its objectives. The results of the evaluation will be used to modify the program announcement to ensure that all elements identified as contributing to the success of a program are part of all future short-term training programs supported by the Institute. *Frequency of Response:* One-time only.

**Affected Public:** Individuals or households; not for profit institutions; business or other for profit. *Type of Respondents:* Undergraduate and graduate students, research faculty, and mentors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,752; *Estimated Number of Responses Per Respondent:* 1; *Average Burden Hours Per Response:* Training grant director—1.00 hour, research faculty—0.334 hours, accepted students—0.5 hours, and nonaccepted students—0.334 hours; and *Estimated Total Annual Burden Hours Requested:* 1,210. The annualized cost to respondents is estimated at: \$27,928. 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 Ms. Barbara F. James, NHLBI Minority Programs Coordinator, Office of Science and Technology, NHLBI, NIH, 31 Center Drive, MSC 2482, Bethesda, Maryland 20892, or call non-toll-free number (301) 402-3421 or E-mail your request, including your address to: <Jamesb@nih.gov>.

**COMMENTS DUE DATE:** Comments regarding this information collection are

best assured of having their full effect if received on or before December 23, 1996.

Dated: October 17, 1996.

Shelia E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96-27328 Filed 10-23-96; 8:45 am]

BILLING CODE 4140-01-M

**Proposed Collection; Comment Request; Pilot Research for Epidemiologic Studies of Migrant and Seasonal Farmworkers**

**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:* Pilot Research for Epidemiologic Studies of Migrant and Seasonal Farmworkers. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* A pilot study will be conducted to evaluate the ability to trace farmworkers over extended periods of time, to determine cancer diagnosis and treatment patterns among migrant and seasonal farmworkers, and to assess the reliability of farm work histories from farmworkers and from their spouses. The information will be used by the NCI to identify the most appropriate study design, case ascertainment procedures, and exposure assessment methods for a full-scale epidemiologic study of cancer among migrant and seasonal farmworkers. Determining the feasibility of using automated data collection techniques to obtain occupational histories from farmworkers will be part of this project. *Frequency of Response:* One-time study. *Affected public:* Individuals or households. *Type of Respondents:* Farmworkers and relatives. The annual reporting burden is as follows:

Type of respondents	Estimated No. of respondents	Estimated No. of responses per respondent	Average burden hours for response	Estimated total annual burden hours requested
Farmworkers .....	77	1	.333	26
Farmworkers with family history of cancer .....	67	1	.167	11
Farmworkers' relatives with cancer .....	33	1	.333	11
Farmworkers and spouses .....	53	1	1.000	53