Dated: October 9, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–25248 Filed 10–12–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request (30-Day FRN); Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 July 16, 2012 (FR 77, 41791) and allowed 60-days for public comment. One public comment was received and a response was sent. The comment referenced alternative research that is unrelated to cancer screening. 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.

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 Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3100, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301–496–8544 or email your request, including your address to: bergc@mail.nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Proposed Collection: Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO), OMB No: 0925–0407, Expiration Date 9/30/2014, Revision, National Cancer Center (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This trial was designed to determine if screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 255,700 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then through 2014. During the first approval period a pilot study was conducted to evaluate recruitment methods and data collection procedures. Recruitment was completed in 2001, screening was completed in 2006, and data collection continues through 2016. When participants enrolled in the trial they agreed to be followed for at least 13 years from the time of enrollment. In 2011, participants were re-consented for at least an additional five years of follow-up. The current number of respondents is limited to the approximately 94,000 participants being actively followed up. This is down from the initial total. The reports on screening and prostate, lung, colorectal and ovarian cancer mortality based on this trial have been published in peer review medical journals. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 31,813.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hrs)	Total burden hours
Male and Female Participants	ASU	94,000	1	5/60	7,833
	Script for ASU Non-response	3,760	1	5/60	313
	HSQ	2,000	1	5/60	167
	MUQ	94,000	1	15/60	23,500
Total					31,813

Dated: October 5, 2012.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, NCI, NIH.

[FR Doc. 2012–25184 Filed 10–12–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Recipient Epidemiology and Donor Evaluation Study-III (REDS–III) Request for Generic Clearance

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: Recipient Epidemiology and Donor Evaluation Study-III (REDS–III). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The objective of the Recipient Epidemiology and Donor Evaluation

Study-III (REDS–III) program is to ensure safe and effective blood banking and transfusion medicine practices through a comprehensive, multifaceted strategy involving basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks. The conduct of epidemiologic, survey, and laboratory studies is the cornerstone of REDS–III and its predecessors, the REDS and REDS–II programs. Over the past 20 years, the National Heart, Lung, and Blood Institute (NHLBI) REDS programs have proven to be the premier research programs in blood collection and transfusion safety in the United States. Successive renditions of the REDS programs have built upon the many successes that this research network has realized over the years while being responsive to changing research and clinical needs, and adapting to emerging priorities. Research findings have served to improve the screening of donors and collected blood products, blood banking practices, diagnoses, and the basic science principles of transfusion medicine.

While significant progress has been made, transfusion therapy—a very commonly used therapy affecting about six million recipients annually in the U.S.—remains one of the least understood medical procedures. REDS–II conducted studies of blood donor health but much more needs to be learned, including how donor genetic or environmental factors may affect the quality of collected blood components and influence non-infectious transfusion complications in recipients. Additionally, there is always the potential that a new, emerging or re-emerging infection may pose a threat to the safety of the U.S. blood supply. Much of the success of the REDS programs was due to their ability to respond in a timely fashion to potential blood safety threats such as West Nile Virus (WNV) in 2002 or Xenotropic Murine Leukemia Virus Related Virus (XMRV) in 2009. Globally, the threat of HIV and other blood-borne infections to blood safety remains real and has to be closely monitored. Therefore, continuing collection of new scientific evidence through REDS–III is both critical to public health in the U.S. and to countries struggling with the HIV epidemic where blood safety and availability are major concerns. Additionally, the research areas encompassed in REDS–III have been and continue to be hypothesis generating, leading to the development of new basic and translational research projects with implications well beyond the fields of blood banking and transfusion medicine. REDS–III has also been charged with the tasks of education and training and integration of these components in a transfusion medicine research network.

With this submission, the REDS–III Study seeks approval from OMB to develop research studies with data collection activities using focus groups, cognitive interviews, questionnaires and/or qualitative interviews following all required informed consent procedures for respondents and parents/caregivers as appropriate. With this generic clearance, study investigators will be able to use the OMB-approved data collection methods where appropriate to plan and implement time sensitive studies. Such studies that fall within the overall scope of this submission will be subjected to expedited review and approval by OMB before their implementation. Additionally, studies are reviewed by an NHLBI Observational Study Monitoring Board (OSMB) and by all relevant IRBs.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Males and females 16 years old or older. The annual reporting burden is as follows: *Estimated Number of Respondents:* 6,882; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 1 hour; *Estimated Total Annual Burden Hours Requested:* 6,826. The annualized total costs to all respondents except for the Brazil and South Africa studies are estimated at $53,964 (based on $9.00 per hour). The annualized total cost to all respondents for the Brazil and South African studies is $2,940. There are no capital, operating, or maintenance costs to the respondents.

ESTIMATED BURDEN HOURS FOR PROPOSED EXAMPLE STUDIES TO BE CONDUCTED UNDER THIS CLEARANCE

Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Summary of Burdens	6,882	1	0.25–1 hour	6,826

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301–435–0065, or Email your request to: *glynnsa@nhlbi.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: August 24, 2012.

Keith Hoots,

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

Dated: October 1, 2012.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2012–25247 Filed 10–12–12; 8:45 am]

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