[NIH Billing Code 4140-01-P]

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: 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 E-mail 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_____

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Keith Hoots, MD

Director, Division of Blood Diseases and Resources

National Heart, Lung, and Blood Institute, NIH

Dated: ___October 1, 2012_____

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Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

[FR Doc. 2012-25247 Filed 10/12/2012 at 8:45 am; Publication Date: 10/15/2012]