

The annualized cost to respondents is estimated at \$308,218, assuming respondents time at the rate of \$22 per hour and healthcare provider time at the rate of \$53 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 Ms. Shari Eason Ludlam, MPH, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7913, Bethesda, MD 20892-7934, or call non-toll-free number 301-402-2900 or Email your request, including your address to: [Ludlams@nhlbi.nih.gov](mailto:Ludlams@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: January 25, 2013.

**Michael Lauer,**

*Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health.*

Dated: January 28, 2013.

**Lynn W. Susulske,**

*Government Information Specialist, Freedom of Information and Privacy Act Branch, NHLBI, National Institutes of Health.*

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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:* Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** in Volume 77, No. 199/ Monday, October 15, 2012, pages 62518-62519, and allowed 60-days for public comment. No comments have been received. 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.

*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:*

Focus Groups: 1 per respondent;  
 Cognitive Interviews: 2 per respondent;  
 Respondent Surveys: 3 per respondent.  
*Average Burden of Hours per Response:*  
 Focus Groups: 1.5 hours per respondent;  
 Cognitive Interviews: 1 hour per respondent;  
 Respondent Surveys: 20

minutes per respondent *Estimated Total Annual Burden Hours Requested:* 7,532. The annualized total costs to all respondents are \$66,288. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Focus Groups .....	300	1	1.5	450
Cognitive Interviews .....	500	2	1.0	1,000
Respondent Surveys .....	6,082	3	.33	6,082
<b>Total .....</b>	<b>6,882</b>			<b>7,532</b>

*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.

*Direct Comments To OMB:* 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: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH. 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](mailto:glynnsa@nhlbi.nih.gov).

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

Dated: January 13, 2013.  
**Keith Hoots,**  
*Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH.*  
 Dated: January 13, 2013.  
**Lynn Susulske,**  
*NHLBI Project Clearance Liaison, National Institutes of Health.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Request for Comment: Input on Recommendations from the Council of Councils Working Group on Use of Chimpanzees in NIH-Supported Research**

**SUMMARY:** The National Institutes of Health (NIH) Council of Councils received and adopted the recommendations and Report of the NIH Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research on January 22, 2013. The report is posted on the NIH Web site at [http://dpcpsi.nih.gov/council/working\\_group\\_message.aspx](http://dpcpsi.nih.gov/council/working_group_message.aspx). The agency will consider the recommendations contained in the report as the agency formulates policy. The NIH also announces the opening of a Request for Comment (RFC) period to collect input on the recommendations from interested parties. Comments will be accepted until Saturday, March 23, 2013, via the comment database at <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31>. In the interim, NIH will continue to apply its policy on Research Involving Chimpanzees (see NOT-OD-12-025; <http://grants.nih.gov/grants/>

[guide/notice-files/NOT-OD-12-025.html.](http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31))

**DATES:** Responses to this RFC will be accepted through 11:59 p.m. EST Saturday, March 23, 2013.

**ADDRESSES:** All comments should be submitted electronically to <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31>.

**FOR FURTHER INFORMATION CONTACT:** The Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health at [dpcpsi@od.nih.gov](mailto:dpcpsi@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The use of animals in biomedical and behavioral research has enabled scientists to identify new ways to treat illness, extend life, and improve health and well-being. Chimpanzees are our closest relatives in the animal kingdom, providing exceptional insights into human biology and requiring special consideration and respect. While used very selectively and in limited numbers for biomedical research, chimpanzees have served an important role in advancing human health in the past. However, new methods and technologies developed by the biomedical community have provided alternatives to the use of chimpanzees in several areas of research.

In December 2010, the NIH commissioned a study by the Institute of Medicine (IOM) to assess whether chimpanzees are or will be necessary for NIH-funded biomedical and behavioral research. A year later on December 15, 2011, the IOM issued its findings, with a primary recommendation that the use of chimpanzees in research be guided by a set of principles and criteria. The committee proposed three principles to analyze current and potential future research using chimpanzees: