Supporting Statement for Request for Clearance:

NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY (NBCUS)

OMB No. (Prior 0990-0313)

Contact Information:

Richard Henry, ML, MPH, MT (ASCP)^{CM}
Deputy Director, Blood Policy & Programs
Office of HIV/AIDS & Infectious Disease Policy
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
(Project Officer)
330 C Street, SW, Suite L100
Washington, DC 20024
(202) 795-7615
richard.henry@hhs.gov

March, 2018

SUPPORTING STATEMENT

NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY (NBCUS)

This request is for OMB emergency clearance for the National Blood Collection and Utilization Survey (NBCUS, prior OMB 0990-0313). The NBCUS is a biennial survey of the blood collection and utilization community to produce reliable and accurate estimates of national and regional collections, utilization and safety of all blood products. The 2017 NBCUS is funded by Department of Health and Human Services (DHHS/OASH) and performed by CDC. In previous years, a similar survey was performed under the auspices of the National Blood Data Resource Center (NBDRC), a private subsidiary of AABB (formerly known as the American Association of Blood Banks), with private funding. In 2005, 2007, 2009, and 2011 the survey was funded by DHHS (OASH) and performed under contract by AABB. In 2013 and 2015, the survey was funded by OASH and performed by CDC. Two sections of the survey involving Tissue Products and Cellular Therapy Products (human cells and tissues) were removed entirely from this survey; otherwise, the remaining questionnaire sections of the 2017 NBCUS are not significantly different from previous 2013 and 2015 versions of the survey and is being submitted to the OMB as an emergency PRA approval (prior control number is OMB 0990-0313).

In addition to generating national estimates of collection and utilization, the 2017 survey, as with the previous 5 iterations in 2007, 2009, 2011, 2013, and 2015 includes questions to specifically identify and collect baseline data to support efforts towards a real-time biovigilance transfusion safety monitoring system. The 2017 version will

support data needed for Blood Safety Objectives of the HHS Healthy People 2020 program within the Office of Disease Prevention & Health Promotion (ODPHP).

The survey questionnaire will be mailed to approximately 2,800 institutions that include hospitals and blood collection facilities selected from the American Hospital Association (AHA) annual survey database and AABB member list of blood collection facilities. The survey includes a core of standard questions on blood collection, processing, and utilization practices to allow for comparison with data from previous surveys. Questions to specifically address emerging and developing issues and technologies in blood collection and utilization are included.

A. Justification

A1. Circumstances Making the Collection of Information Necessary

Under the authority of Section 301 of the Public Health Service Act (42 U.S.C.241), as identified in the 1997 HHS Blood Action Plan, and twice in the Advisory Committee on Blood Safety and Availability's (ACBSA) recommendations to the Secretary, there is a need to provide national policy makers with current supply and demand data. The ACBSA was established by HHS in 1997 to provide policy advice to the Secretary and the Assistant Secretary for Health and was amended in 2012 to include tissues, becoming the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). The advice of the committee is partly dependent on the analysis of relevant blood collection and utilization data which is also widely distributed to and used by the transfusion medicine community. To that end, the Office of the Assistant Secretary for Health (OASH) is responsible for conducting a biennial cross-sectional national blood

products survey. Previous private and government financed versions of the NBCUS have successfully surveyed greater than 90% of the U.S. blood collection and processing facilities and more than 2,300 hospital-based transfusion blood banks in the United States.

A2. Purpose and Use of Information Collection

The objective of the NBCUS is to produce reliable and accurate estimates of national and regional collections, utilization, and safety of all blood products – red blood cells, fresh frozen plasma, and platelets. This survey will significantly improve the federal government's capacity to understand the dynamics of blood supply, safety and availability, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2017 survey is to help the federal government continue to monitor trends in blood availability, which is critical to ensure an adequate supply of safe blood in the United States. In addition to use by the federal government, data collected in this survey will be of practical use to the blood banking and hospital transfusion services communities. In previous years the comprehensive survey report published on blood collection and transfusion related activities has been widely used by the transfusion medicine community. Broad dissemination of the survey findings through publication of this survey report and scientific papers in peer reviewed journals has significantly benefited HHS Agencies and the transfusion medicine community at large by furthering community discussion of key findings. Data from the 1997 and 1999 surveys have been used in testimony before congress. Data from the 2005 NBCUS was used extensively in the preparation of the Transfusion and Transplantation Safety

document by DHHS. Additionally the 2005 and 2007 survey provided baseline information for establishing the Blood Availability and Safety Inventory System (BASIS).

Each question in the proposed survey relates to the analysis objectives detailed in Section A 16 and lists the questions by survey domains and provides justification. The general categories of information to be collected are:

- General information
- Blood collection, processing and testing
- Blood transfusion
- Special procedures and product disposition

A3. Use of Improved Information Technology and Burden Reduction

Record-keeping systems of blood banks and hospitals have evolved to support electronic response to the NBCUS. Purposeful steps have been taken to work with the blood industry to pattern the NBCUS data elements upon the data traditionally collected by the private sector for their own business purposes (e.g., policy, practices, etc.). Efforts made to minimize respondent burden are as follows:

- The questionnaire is divided into color coded sections that clearly identify sections that blood banks/ hospitals/cord blood banks need to complete or skip.
- Appropriate sections of the survey instrument will be emailed to each institution.
- The questionnaire contains easy to read instructions and skip patterns to avoid having respondents answer unnecessary questions.
- The questionnaire contains a glossary of definitions to assist the respondent.

To ensure that the most relevant supply and utilization issues are addressed fully, critical questions from the full survey instrument will be available in the form of a supplemental web survey on the CDC/NBCUS website. Institutions either unwilling or unable to participate in the full survey will be asked to respond to this short list of questions.

A4. Efforts to Identify Duplication and Use of Similar Information

Reliable data on blood collection and utilization on a national scale are not available from any other source. While segments of the blood collection industry collect some information, it is often proprietary and not available to the government or the public at large. The 2017 survey will contain all core questions asked on previous national surveys (NBCUS) to allow for comparison of data. HHS, CDC and AABB previously consulted with its various expert committees, consisting of members who are leading researchers in the field, to identify and develop universal questions that are of interest to the transfusion medicine community (unavailable elsewhere as a national set).

A5. Impact on Small Businesses or Other Small Entities

Very few of the survey respondents are small hospitals. Hospitals performing less than 100 surgeries are excluded from the sample because they contribute little to either collections or blood product utilization. Nevertheless, to help all institutions complete the survey, a 24 hour toll-free helpline will be provided to answer questions related to the survey.

A6. Consequences of Collecting Information Less Frequently

The NBCUS is administered bi-annually. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of US blood collections and transfusions, for understanding the dynamics of blood safety and availability. These data have become even more crucial with the need to help insure patient safety by monitoring and identifying errors in transfusion medicine and related therapies.

A7. Special Circumstances Relating to Guidelines of 5CFR 1320.5

The proposed data collection is consistent with 5CFR 1320.5. There are no special circumstances applicable to the survey.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

There have been several meetings outside of DHHS to conceptualize and design sections of this survey. Various AABB expert committees such as the Transfusion Transmittable Diseases Committee, the Intra-organizational Task Force on Disasters, the Blood Products Working Group and the Coding and Reimbursement Committee were consulted in the development of the questionnaire. In addition, experts from the Centers for Medicare & Medicaid Services (CMS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC) and the Health Resources and Services Administration (HRSA) were consulted on relevant sections of the questionnaire.

A9. Explanation of Any Payment or Gifts to Respondents

Respondents will not receive any gifts or payments.

A10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to the proposed data collection since respondents are not human subjects, but institutions; and no patient/donor identifiers are collected.

A11. Justification of Sensitive Questions

Information on issues of a sensitive nature involving persons is not being sought. Infectious disease testing results are reported in aggregate only.

A12. Estimates of Annualized Burden Hours and Cost

The burden for the NBCUS survey is summarized in the table below. Each institution that is asked to complete the survey questionnaire is considered to be a respondent. The respondents to this survey are hospitals, blood collection centers and cord blood banks. The number of eligible respondents is 2,800. It is estimated that each respondent will spend about 60 minutes (1 burden hour/year) completing the questionnaire. The hourly burden estimates are based on previous years' experience administering the survey.

Estimate Annualized Burden Table

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Hospitals, blood collection centers, cord blood banks	2,800	1	1	2,800

Burden Cost

The average annualized response burden cost to respondents is estimated to be $ 106,400 based on an hourly wage of $38 per hour. The hourly wage estimate is based on the Bureau of Labor Statistics' National Compensation Survey mean hourly wage data for health related occupations in 2010.

Table A12 - 2: Annualized Cost to Respondents			
Type of respondents	Total annual response burden hours	Hourly wage rate	Respondent cost
Hospitals, blood collection centers, cord blood banks	2,800	$38.00	$106,400

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record keepers

There is no other capital or start up costs, and no maintenance or service cost components to report.

A14. Annualized Cost to the Federal Government

All survey operations including survey development, data collection, analysis, and preparation of the final report are contracted internally to the CDC by HHS/OASH. The total cost of this fixed price agreement is $485,000. The annualized cost to the federal government is $242,500.

A15. Explanation for Program Changes or Adjustments

This collection is being submitted for OMB approval for emergency (after three previous and successful 3-year approval periods); only very slight changes were made to some of the survey questions to facilitate usability and all other aspects of the program remain the same.

A16. Plans for Tabulation and Publication and Project Time Schedule

The time table for key activities for the 2017 survey is as follows:

Table A 16: Timeline	
4/06/2018	Receive OMB clearance
4/09/2018	Begin data collection for 2011 survey (collect CY 2010 data)
6/08/2018	End data collection
6/15/2018	close out
7/16/2018	End data processing and create dataset
8/01/2018	Begin data analysis
11/19/2018	Publish final summary report

Statistical tabulations of results for each question will be presented. These will be broken down by institution type, services provided, USPHS region, etc. Selected examples of types of analyses proposed include:

- Analyses of trends in the U.S. blood supply
- Total supply of blood collected in the U.S. broken down by type (Whole blood, Allogeneic, Whole blood autologous, WB directed, RBC apheresis, platelets, plasma etc)
- Total transfusions in the U.S. broken down by type (Whole blood, RBC, platelets, Non-RBC components transfused etc)
- National estimates of all whole blood and blood component units outdated by blood centers and hospitals
- Component modifications – Irradiation, leukocyte reduction by blood centers and hospitals
- Number of adverse events (TRALI, TACO, Hemolysis, Allergic reactions etc)

After final validation of results a summary report (or peer reviewed journal article) of findings from the survey will be published. The 2005, 2007, 2009, 2011, 2013, and 2015 Nationwide Blood Collection and Utilization reports are available at www.hhs.gov/ash/bloodsafety.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption is not requested. The OMB clearance number and expiration date will be displayed on the upper right hand corner of the survey.

A18. Exceptions to Certification of Paperwork Reduction Act Submissions

The data encompassed by this survey will fully comply with all guidelines of 5 CFR 1320.9 and no exception is requested to certification for Paperwork Reduction Act Submission.