

National Blood Collection and Utilization Survey

Request for OMB approval of a New Information Collection

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Supporting Statement A

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Table of Contents

1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of Information Collection.....	4
3. Use of Improved Information Technology and Burden Reduction.....	5
4. Efforts to Identify Duplication and Use of Similar Information.....	5
5. Impact on Small Businesses or Other Small Entities.....	5
6. Consequences of Collecting the Information Less Frequently.....	5
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.	6
9. Explanation of Any Payment or Gift to Respondents.....	6
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	6
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	6
12. Estimates of Annualized Burden Hours and Costs.....	6
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	7
14. Annualized Cost to the Government.....	7
15. Explanation for Program Changes or Adjustments.....	7
16. Plans for Tabulation and Publication and Project Time Schedule.....	8
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	8
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	9
Attachments.....	9

- **Goal of the study:** The objective of the NBCUS is to produce reliable and accurate estimates of national and regional collections, utilization, and safety of blood products.
- **Intended use of the resulting data:** This survey is intended to improve and enhance the federal government's efforts related to infectious disease risk mitigation to the U.S. blood supply. Data from the survey will further enable the federal government and relevant stakeholders to understand dynamics of blood supply and demand, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2025 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. Data collected in this survey will be of practical use to the blood banking and hospital transfusion services communities in the private sector to advance quality standards and procedures.
- **Methods to be used to collect:** We will draw a stratified, single stage sample of blood collection establishments and hospitals performing inpatient transfusions with equal probability within each stratum. We will stratify hospitals from the American Hospital Association's annual survey of hospitals by annual inpatient surgical volume and select all (100%) hospitals in larger size strata. Forty percent (40%) of hospitals in the lowest surgical volume category will be randomly sampled. To maximize response rate as well as response quality, a unique survey link will be sent via email to a confirmed contact for each facility with multiple follow-up efforts. These will include email reminders, paper letters via mail, and/or phone calls to non-respondent facilities.
- **The subpopulation to be studied:** The population of inference for the 2025 NBCUS will be all blood collection establishments and facilities performing inpatient transfusions in the United States. The target population for the 2025 NBCUS will consist of all blood collection centers and all hospitals subject to certain ownership, service and location criteria. Some practical restrictions are also placed on the target population – specifically, hospitals reporting fewer than 100 inpatient surgeries per year are excluded since these may contribute little to either collections or blood product utilization overall.
How data will be analyzed: National estimates will be calculated for the number of blood and blood components collected, distributed, transfused, rejected on infectious testing, infectious disease markers, outdated units, blood donor characteristics, donation deferrals, component costs, transfusion-associated adverse reactions, and use of infectious disease risk mitigation strategies. Weighting and imputation will be used for nonresponses and missing data, respectively.

1. Circumstances Making the Collection of Information Necessary

This request is for OMB approval of a new information collection request, the 2025 National Blood Collection and Utilization Survey (NBCUS), OMB No. XXXXXXXX.

The Office of the Assistant Secretary for Health (OASH) within HHS has been historically responsible for conducting a biennial cross-sectional national blood products survey. In addition, the former Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) identified a need to provide national policy makers with current blood supply and demand data. The ACBTSA was

established to provide policy advice to the Secretary and the Assistant Secretary for Health. The advice of ACBTSA has been partly dependent on the analysis of relevant blood collection and utilization data, which is also widely distributed to and used by the transfusion medicine and blood banking community. This data collection is authorized by the following: Section 301 of the Public Health Service Act (42 U.S.C. 241); 42 U.S. Code § 247d–12 - Coordination and collaboration regarding blood supply; and Consolidated Appropriations Act, 2023 Section 2233 (Attachment 1-3).

The NBCUS is conducted biennially. Since 2013, in close collaboration with OASH, the NBCUS has been performed by the Centers for Disease Control and Prevention (CDC), which has the requisite technical and scientific resources to conduct the survey. The response rates for the 2023 NBCUS were 96.2% (51/53) for community-based blood collection facilities, 90.3% (65/72) for hospital-based blood collection facilities, and 85.7% (2195/2561) for transfusing hospitals. Based on the previous iterations of the NBCUS, we expect an overall response rate of almost 85% across all types of facilities.

2. 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 blood products – red blood cells (RBCs), fresh frozen plasma, and platelets. This survey will significantly improve the federal government’s capacity to understand the dynamics of blood supply and demand, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2025 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 the private sector to advance quality standards and procedures. Broad dissemination of the survey findings through publication of reports (2005-2011 surveys) and open access scientific papers in peer review journals (2013-2023 surveys) has significantly benefited not only HHS, but the transfusion medicine community at large by furthering community discussion of key findings. Data from surveys have informed policy across HHS operating and staff divisions.

Each question in the proposed survey relates to the analysis objectives detailed in Section A-16 and lists the questions by survey domains. The general categories of information to be collected are: General information; Blood collection; and Blood transfusion.

3. Use of Improved Information Technology and Burden Reduction

The person completing the electronic survey will be given a unique login and password. Efforts to minimize respondent burden are as follows:

- The survey is divided into two sections (blood collection and blood transfusion) for respondents to complete or skip.
- The survey contains easy to read instructions and skip patterns to avoid having respondents answer unnecessary questions.

- The survey contains a glossary of definitions to assist the respondent.
- A Survey Helpline number will be provided. The toll-free helpline will field inquiries related to the survey and will be available 24 hours a day to answer questions related to the survey.
- For institutions that have not responded, an abbreviated version of the survey containing critical items will be distributed. The survey will be made available both electronically and in paper form.

4. Efforts to Identify Duplication and Use of Similar Information

The NBCUS has been conducted by HHS/OASH and CDC since 2005. 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.

5. Impact on Small Businesses or Other Small Entities

The target population consists of U.S. blood collection facilities and transfusing hospitals. Every effort is made to minimize the burden on small businesses when collecting information.

6. Consequences of Collecting the Information Less Frequently

The NBCUS is administered biennially. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. 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 ensure patient safety by monitoring and identifying errors in transfusion medicine and related therapies.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5. There are no special circumstances associated with this data collection activity.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on December 5, 2025, vol. 90, No. 232, pp. 56149-56150 (Attachment 3). CDC did receive public comments related to this notice. A total of 10 comments were received. Responses are imbedded in the public comment document (Attachment 6).

B. During previous survey cycles, CDC and OASH consulted with external stakeholders including experts in blood collection and transfusion regarding survey questions and other matters relevant to public health importance which should be included in this activity. For the present cycle, CDC engaged in informal discussions with external stakeholders from the blood collection and transfusion communities regarding matters of public health importance that should be included in this activity.

9. Explanation of Any Payment or Gift to Respondents

Remuneration of respondents is not provided.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply since respondents are not human subjects, but institutions; and no patient/donor identifiers are collected. Data identifying institutions will be kept private to the extent allowed by law.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required.

A Human Subjects Determination is included (Attachment 10).

Justification for Sensitive Questions

Information on issues of a sensitive nature involving persons is not being sought.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The burden for the NBCUS survey is summarized in the table below (estimated using references to 2023 NBCUS). Each institution that is asked to complete the survey is considered to be a respondent. The respondents to this survey are transfusing hospitals, blood collection centers and community blood banks. The number of respondents is 2,635. It is estimated that each respondent will spend about 210 minutes (3.5 burden hours total; or 1 hour and 45 minutes burden hour/year) completing the questionnaire. The hourly burden estimates are based on 210 minutes from previous years' experience administering the survey and accounts for the revision to questions in the NBCUS.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Transfusing hospitals	2025 NBCUS	2478	1	1.75 hrs	4337
Hospital blood banks	2025 NBCUS	104	1	1.75	182
Community-based blood centers	2025 NBCUS	53	1	1.75	93
Total	2635 respondents				4612

B. Estimated Annualized Burden Costs

The average annualized response burden cost to respondents is estimated to be \$184,249 based on an hourly wage of \$39.95 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 2024.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospitals, blood collection centers	2025 NBCUS	4612	\$39.95	\$184,249.40
Total				\$184,249.40

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

All survey operations including survey development, data collection, analysis, and preparation of the final report are conducted by CDC. OASH has committed support via an Interagency Agreement (IAA) at ~\$250,000 annually.

15. Explanation for Program Changes or Adjustments

This collection is being submitted for OMB approval as a new collection tool; however, the 2025 survey only has slight revisions to core questions from the 2023 survey submitted by OASH and approved by OMB under [0990-0313](#). The draft 2025 survey is the same length as the 2023 survey. It is estimated that each facility takes an average 1.75 hours to complete the survey.

16. Plans for Tabulation and Publication and Project Time Schedule

[For collections of information whose results are planned to be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions. The time required for “data/information collection” activities should align with the length of time for which OMB approval is requested. Ensure to leave enough time to allow for delays and for unforeseen circumstances. For recurring data/information collections, state the number of years requested for clearance.]

The timetable for key activities for the 2025 survey is as follows:

Timeline	
TBD	Receive OMB clearance
March 2026	Finalize NBCUS 2025 in REDCap

April 2026	Confirm contact list
June 2026	Begin data collection for 2025 survey
October 2026	End data collection
October 2026	Begin data analysis
2027	Publish final comprehensive report

Statistical tabulations of results for each question will be presented. These will be broken down by institution type, services provided, United States Public Health Service (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 (e.g., whole blood (WB), allogeneic, WB autologous, WB directed, RBC apheresis, platelets, plasma)
- Total transfusions in the U.S. broken down by type (e.g., WB, RBC, platelets, non-RBC components transfused)
- 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 repeat reactive and confirmed positive first time and repeat allogeneic donors by infectious disease marker type
- Rates of confirmed positives and false positives by bacterial testing methods
- Number of adverse events (e.g., Transfusion-related acute lung injury (TRALI), Transfusion-associated circulatory overload (TACO), Hemolysis, Allergic reactions, etc.)

After final validation of results a comprehensive report of findings from the survey will be published. The 2005 through 2021 Nationwide Blood Collection and Utilization reports are available at <https://www.hhs.gov/oidp/topics/blood-tissue-safety/surveys/national-blood-collection-and-utilization-survey/index.html>.

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Published 60-Day FRN
- 2a-2c. Authorizing Legislation

3. 30-Day FRN
4. Information Collection instrument
5. Human Subjects Determination
6. Public Comment and Responses