United States Food and Drug Administration

Donor Risk Assessment Questionnaire for the Food and Drug Administration (FDA)/National Heart, Lung, and Blood Institute (NHLBI)-Sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation (RFE)

OMB Control No. 0910-0841

SUPPORTING STATEMENT

Terms of Clearance: In its last approval, OMB encouraged FDA to monitor breakoff closely to help ensure adequate data quality. We have monitored breakoff during the past three years the questionnaire has been implemented. We found that we did not have a problem with breakoff. We believe our data quality is high.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   The Food and Drug Administration (FDA) is requesting OMB approval of the questionnaire-based information collection discussed below:

   TTIMS is a collaboration of the Food and Drug Administration (FDA), National Heart Lung and Blood Institute (NHLBI), Department of Health and Human Services, Office of the Assistant Secretary of Health (HHS/OASH) and large US blood collection systems in the US working together to create a representative, stable, donor hemovigilance program for monitoring current risk factors for transfusion-transmissible infections (TTI) in blood donors using an analytical study design. This capability has been unavailable in the United States until the Transfusion-Transmissible Infection Monitoring System (TTIMS) was established in 2015. Blood establishments participating in TTIMS collect nearly 60% of the nation's blood supply. These include the American Red Cross (ARC), Blood Systems, Inc. (BSI), New York Blood Center (NYBC), and OneBlood.

   TTIMS is establishing critical hemovigilance capability for the US through a multi-pronged approach including: 1) The ongoing longitudinal compilation of demographic, donor screening and confirmatory test data that are collected by participating blood centers as part of regulated operational procedures, These data will allow monitoring of the incidence and prevalence of blood donor TTIs; 2) Additional testing of the human immunodeficiency virus (HIV)-positive blood samples that are collected operationally by participating blood centers to better characterize recency of HIV infection; and 3) Monitoring of the distribution of risk factors for HIV and incident HBV and HCV-positive donors who are identified through blood donor screening. The first two TTIMS components have now been established and are supporting incidence and prevalence calculations. The FDA is requesting extension of OMB approval of TTIMS, with certain modifications to the questionnaire.

   Recently, the SARS-CoV-2/COVID-19 pandemic has impacted blood and blood product

donations significantly due to cancellations of blood drives and social distancing recommendations. As a result, we have revised the currently approved collection instrument for the collection of information and have included Agency guidance. On April 2, 2020, FDA issued a revised guidance document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry" dated April 2020 (available at: https://www.fda.gov/media/92490/download). To encourage more donations, the Food and Drug Administration (FDA) revised several donor deferral recommendations. Revisions include reduction of deferral periods for donors who have had recent tattoos and piercings, male donors who have had sex with another man, and female donors who have had sex with men who have had sex with another man. The deferral period for these groups was reduced from 12 months to 3 months from time of last tattoo, piercing, or relevant sexual contact. TTIMS functions as a donation biovigilance tool and the current OMB-cleared version of the Risk Factor Questionnaire (RFQ) asks eligible participants about these exposures in the last 12 months. To account for the modifications to the donor eligibility rules, the TTIMS program seeks approval to revise the RFQ to ask about these exposures in the last 3 months, in addition to maintaining the existing questions. Both 12-month and 3-month questions will provide important risk factor information. The 3-month questions are identical in format and structure to 12-month questions, but for the change to the time interval. The additional question about sexual contact in the last-3 months will be accompanied by additional question about condom use during the same 3-month period. The new questions are 37b, 37c, 42b, 42c, 57b, 60b, 62b, and 69b.

Another change is about use of HIV pre-exposure prophylaxis (PrEP). In question 14 this is described as an "antiviral medication taken daily". Since the development of this question on the first OMB-cleared version of the risk factor questionnaire, an expanded understanding of the way PrEP is being used has been reported in the literature. In additional to taking a daily dose, on demand use is increasingly common. On demand use is defined using several terms, including "Intermittent", "Event-Driven," "Sex-Driven," "On Demand," or "2-1-1" PrEP. (Note, 2-1-1 describes the days PrEP is taken: 2 days before sex, the day of sex, and one day after sex.) We have added a sub-question (14b) to question 14 that will inquire about the way respondents have used PrEP, if they report using PrEP. In addition, we want to change the question to remove the phrase "take daily", as this is no longer the only way PrEP is used. We have revised the description of PrEP in this question to "*PrEP is an antiviral medication taken to reduce a person's chance of getting HIV*" and to offer answer options covering the ways PrEP is currently being used.

The final changes that we seek clearance for are the inclusion of answer options in two existing questions based in the experiences of research interviewers who conduct the telephone interviews. Question 8 is an open-ended question on occupation so the entire list of answer options is not read to participants. We added "Student" as an option for interviewers to check, instead of writing this option into the "Other" box. The other additional answer option is to question 47.1 which asks about substances a participant has injected. Adding "Opiates/Opioids" as an answer option will improve the accuracy of the substance options that are inquired about in this question. Making these available as pre-

specified responses will reduce the burden on interviewers to manually add responses, thus contributing to high data quality, lead to fewer errors, and may contribute to a reduction in survey response time burden for participants.

The research interviews report the time to complete the currently approved interview is 20 to 30 minutes. With the addition of the new questions, we estimate that it will take respondents 30 minutes, on average, to complete the revised interview.

2. Purpose and Use of the Information Collection

FDA intends to interview blood donors to collect risk factor information associated with testing positive for transfusion-transmissible infections (TTI). This collection of information is part of a larger initiative called TTIMS, which is a collaborative project funded by FDA, the NHLBI, and HHS/OASH with input from other agencies in HHS including the Centers for Disease Control and Prevention (CDC). FDA will use these scientific data collected through such interview-based risk factor elicitation of blood donors to monitor and help ensure the safety of the United States blood supply. FDA provided a Program Overview of TTIMS at the Blood Products Advisory Committee meeting on March 21, 2019. The slides from that meeting are included as an attachment to this ICR. Pages 13-17 of the slides provides TTIMS Analysis Strategies.

TTIMS consists of two coordinating centers: The Donation Database Coordinating Center (DDCC) and the Laboratory and Risk Factor Database Coordinating Center (LRCC). The American Red Cross acts as the DDCC and Vitalant Research Institute acts as the LRCC for the study. TTIMS brings together donation and test data acquired during routine blood donation collections at four major US blood systems (American Red Cross, New York Blood Center, OneBlood and Vitalant) with data collected from specialty research studies. Together this data provides critical blood safety and monitoring information on more than 50% of the US blood supply.

The DDCC is responsible for acquiring and validating donor demographic data from the four participating blood systems plus testing results from Creative Testing Solutions, ensuring that the data available from each system are harmonized, and that appropriate consensus positive definitions are consistently applied across sites. The DDCC then analyzes and reports on the prevalence and incidence of HIV, HBV and HCV in US blood donors and donations, with special attention paid to temporal and demographic changes and trends. The DDCC also reports positive and false positive donors to the LRCC. The LRCC coordinates the Risk Factor Questionnaire study. The LRCC provides each blood center lists from which donors are interviewed by each center's donor counselors. LRCC compiles and analyses this data. The LRCC also acts as the repository for positive samples and conducts follow-up molecular sequencing, recency and other testing of interest. The American Red Cross participates in both the DDCC and the LRCC activities. See https://www.redcrossblood.org/biomedical-services/educational-resources/science/areas-of-research/donor-recipient-health-epidemiology.html

TTIMS will use similar procedures as the ones used in previous OMB approved information collection "Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance" (OMB control number 0925-0630) to monitor and evaluate risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls. The overall TTIMS program will help identify the specific risk factors for TTI and their prevalence in blood donors, and help inform FDA on the proportion of incident (new) infections among all HIV positive blood donors. Donations with incident infections have the greatest potential transmission risk because they could be missed during routine blood screening. TTIMS will help FDA evaluate the effectiveness of screening strategies in reducing the risk of HIV and hepatitis transmission from at-risk donors. This will be accomplished by evaluating unexpected consequences associated with the most recent change in donor deferral policy such as a relative increase in HIV or hepatitis incidence among donors, or significant quantitative changes in the relative proportions or characteristics of the risk behaviors associated with donor TTI risks as determined by the TTIMS risk evaluation component of the program. These data also will inform FDA regarding future blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals to alternate approaches such as the use of individual risk assessments. Over time, TTIMS may also inform the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

3. Use of Improved Information Technology and Burden Reduction

There are three possible routes of participant contact for the risk factor evaluation which are intended to minimize the burden of participation in the project by allowing donors to participate in the manner that is preferred by each donor.

- The primary route of participation in this project will be by telephone interviews of donors conducted for study data collection by trained donor counselors. Donor counselor-initiated phone contact will occur in which the donor counselors will follow-up to see if the donor received the notification letter and counseling materials mailed to donors using routine blood bank procedures. Donor counselors will attempt to contact donors up to three times by telephone, email, or text message. If the project staff are unable to reach a donor after three attempts the donor will be classified as lost to follow-up.

- Donor-initiated telephone contact following receipt of disease marker testing results and counseling materials sent to the donor via standard mail (HCV and HBV confirmed positive results and for all false positive results). Donors who are notified by mail whether confirmed or false positive are encouraged to call donor counselors to discuss the results and any additional questions the donors may have.

- In-person interviews may occur when a donor returns to the blood center for counseling (expected for HIV-positive donors) but donors who are positive for

other viral markers could also seek in-person counseling. False positive donors may also seek in-person counseling.

The donor counselors will use an internet-based survey questionnaire program to automatically capture donor responses into a consolidated research database. Efforts to minimize respondent burden are described below:

- In-person or telephone interviews conducted using internet-based programs rather than self-administered questionnaire will help reduce respondent burden. Participants will be guided through all questions.

- Questionnaires include built-in skip patterns so that respondents are only asked relevant questions rather than all questions. Also, while the questions for both cases and controls are mostly identical, some questions will only be asked of donors with confirmed positive donations.

- The questionnaire contains risk behavior questions previously used in large-scale CDC surveys, and in the previous OMB approved project "REDS-II Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance" (OMB control number 0925-0630). The content is focused on common and less common routes of viral infection acquisition. The content does not include investigation of new or unproven routes of infection acquisition.

FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

No single comprehensive blood donor surveillance system exists in the United States to monitor TTI in blood donors.

Previous assessments of risk factor profiles among blood donors found to be positive for HIV were funded by CDC for approximately 10 years after implementation of HIV serologic screening of blood donors in the mid-1980s, whereas studies of HCV seropositive donors, funded by NIH, were conducted in the early 1990s. Information on current risk factors in blood donors as assessed using analytical study designs was next evaluated by the "REDS-II Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance" (OMB control number 0925-630). Through a risk factor questionnaire, this study elicited risk factors in blood donors who tested confirmed positive for one of four transfusion-transmissible infections: HIV, HCV, HBV, and Human T-cell Lymphotropic virus. The study also elicited risk factors from donors who did not have any infections (controls) and compared their responses to those of the donors with confirmed infection (cases). Results from the REDS–II study were published in 2015.

Until the completion of the REDS-II study, virtually no contemporary data on behavioral risk factors for the viral infections of interest in the TTIMS program were available.

There are no duplicate sources of such information in the United States. While the CDC) conducted a series of donor risk evaluations in the 1990's, the current focus of CDC is on HIV prevention and treatment and current studies of blood donors are largely limited to participations in investigations of potential HIV transmissions that have occurred through blood products. Similarly, the NHLBI REDS-II program conducted highly successful epidemiologic studies of HIV in blood donors, however, this program was time-limited (incident HIV infections were not observed within the study). The REDS-II program (by design) paved the way for the anticipated longer term TTIMS in numerous ways.

The collection of the proposed information is a vital part of the overall responsibility of the Federal Government and United States blood collection centers to ensure the safety of the national blood supply. FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, biological products, medical devices, tobacco products, our nation's food supply, cosmetics and products that emit radiation. During its July 2, 2013 meeting, the DHHS Blood, Organ, and Tissue Senior Executive Council (BOTSEC), which includes representation by DHHS/OASH, CDC, NIH, Centers for Medicare and Medicaid Services (CMS), Health Resources Services Administration (HRSA), FDA, DHHS/Assistant Secretary for Planning and Evaluation (ASPE), DHHS/Assistant Secretary for Preparedness and Response (ASPR), and Agency for Healthcare Research and Quality (AHRQ), unanimously voted to enhance monitoring of TTIs in the United States by creating TTIMS.

Data collected in this project will be of practical use to the blood banking community and to the Federal Government (See specific aims of the study in Section A.1). In addition to peer-reviewed scientific publication, we anticipate data requests for presentations by Federal and non-Federal agencies, including the FDA Blood Products Advisory Committee, the DHHS Advisory Committee on Blood and Tissue Safety and Availability, the AABB Transfusion-Transmitted Diseases Committee, and the America's Blood Centers Association.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Study participants will be interviewed once only. Donors who agree to participate will be consented and asked to participate in the in-person or telephone interview. There is no follow-up involved. Less frequent collection of data would directly impair efforts to monitor trends in the infection risk factors reported by donors.

There are no technical or legal obstacles to reduce the burden.

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

   There are no special circumstances for this collection of information.

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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *FEDERAL REGISTER* of January 8, 2020 (85 FR 922). We received two comments that were generally supportive of the collection. One comment also contained a specific suggestion that, in analyzing the data after it is collected, we utilize an "underreporting correction factor" identified by the commenter. The comment did not suggest that we make any changes to the Donor Risk Assessment Questionnaire or the information collection requirements. We appreciate the commenter's interest in the accuracy of the TTIMS and will consider the "underreporting correction factor" identified by the commenter when analyzing the data.

9. Explanation of Any Payment or Gift to Respondents

   Confirmed positive (case) and control donors will receive $75 for completing the interview. The participation incentive will be sent to each donor within six weeks following the completion of the interview. The incentives used for the study are justified on the basis of several considerations, as follows:

   - First, the seropositive blood donors under study are a rare and hard-to-reach population. Approximately 1 out of every 40,000 donors has HIV. They represent a tiny fraction of the individuals who donate blood. Maximizing the participation of all donors with HIV infection and newly acquired HBV or HCV infection is particularly important to achieve a representative assessment of contemporary risk factors, i.e., the behaviors that likely led to acquisition of infection before donating blood. Many of the risk behaviors the project is inquiring about on the TTIMS risk factor interview should have been disclosed at the time of blood donation. If disclosed at that time, the disclosure would have made the donor ineligible for donation. TTIMS must overcome the barrier of previous non-disclosure of behavioral risks at the time of the proposed post-donation interview. This situation is different than general population surveys because donors with infection cannot be identified any other way than through donation. There are no other methods to identify these people for the risk factor interview.

   - Second, the incentive contributes to improved disclosure by acknowledging the participants for frank reporting of sensitive and private behavior. As for cases, disclosure of risk behaviors in controls is equally important. In the " REDS-II Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance" high rates of undisclosed risk behaviors in uninfected false-positive (control) donors were

found. For example, 1.7% of uninfected male controls in that study reported they had deferrable MSM behavior. This indicates the project must also overcome barriers to disclosure that are present in control donors.

- Third, the majority of the interviews will be conducted by telephone at the time of first voice contact with the donors. It is very important to use this opportunity to enroll the potential participants in the project and we believe that offering incentives will help the donor counselors and physicians to gain consent for participation. From the experience in previous studies of infectious markers in blood donors, it is best to complete interviews of risks factors during the first voice contact. Payment can help to facilitate the willingness to complete the risk factor questionnaire.

- Fourth, we will be seeking verbal consent to ask the study participants sensitive questions regarding private and personal behaviors. The payment is intended to recognize and thank each participant for taking the time to answer the questions as honestly as possible.

- Fifth, for the OMB-cleared REDS-II risk factor study (OMB control number 0925-630) cases were provided $75 reimbursement. Using the US BLS inflation calculator, (https://data.bls.gov/cgi-bin/cpicalc.pl?cost1=75.00&year1=201012&year2=201703), $75 in 2010 dollars is $83.43 today. As we will conduct the risk factor interviews for at least the next 3 years, we want to be certain to provide a reimbursement consistent with inflation-adjusted amounts and trends, and also reflecting the importance of each case and control interview. Importantly, for operational reasons the largest participating blood collection organization (ARC) is only able to offer reimbursement amounts in increments of $25.

- Sixth, a payment of $75 is consistent with other studies conducted with blood donors as illustrated by the following two examples:

  - An example of the reimbursement amount for donor-related studies is provided for a study of Dengue infection in donors from the ARC, see attached full consent, quoted from the informed consent for that study:

    "Will I be paid for participating?
    You will be compensated $100 for taking part in follow-up testing for dengue virus and completing the questionnaire. In the event that additional testing is requested for a second or multiple visits, if we find that you are likely truly infected with dengue virus, you would receive $150 for each of your additional visits."

    This Dengue study did include a return to the blood center to collect a blood sample and risk factor interview covering topics which are not nearly as sensitive as those planned for the TTIMS risk factor interview.

- For donors who test positive and are requested to come back for additional sample collection, currently ARC offers $300. [Ultrio Plus Study of HIV, HCV, HBV, donor compensation is $300]. This does involve a return to the blood center to collect a blood sample, but does not include risk factor interviews.

Given the previous listed reason and examples of similar studies in blood banking, we believe $75 payment for cases and controls is an appropriate level for the TTIMS risk factor interviews.

10. Assurance of Confidentiality Provided to Respondents

This information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. This ICR involves a citation in the CFR (21 CFR 11.100) that requires firms to submit to FDA a certification in paper form with a traditional handwritten signature. Such submissions to FDA are made via a paper letter, e.g., on a firm's own letterhead.

FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

The TTIMS risk evaluation project procedures are designed to protect the privacy of the participants. Each participating blood center has obtained human subjects approvals from relevant institutional review boards (IRBs) to conduct all aspects of the study. Each IRB has approved the privacy protection procedures we have included in the project. The only persons who will have access to personally identifying information (such as names, phone numbers, and addresses) are the donor counselors and clinicians within each blood collection organization. These personal identifiers are required to be used to properly identify each donor according to standard operational procedures at blood centers and to provide the reimbursement for participation. The information collected in the research databases will include unique project identification numbers. The data transferred to the researchers in this project will not include personally identifying information and from these data it will not be possible to trace back to personally identifying information. All study data will have a code numbers (donation identification number and donor number) instead of the participant's name. Participant names or the project code numbers will not be used in any summaries of the data, public presentations or published reports from this project.

In addition, a Certificate of Confidentiality specifically for the TTIMS project participants was obtained, thus preventing researchers from being legally compelled to release information reported by the participants. The Certificate of Confidentiality was obtained in accordance with Section 301(d) of the Public Health Service Act. This Certificate prevents study staff from being compelled to disclose information that may identify participants by court order or other legal action. This protection lasts forever (even after death) for all project participants.

11. Justification for Sensitive Questions

The purpose of the interview questions is to collect donor demographic and behavioral profile data for comparing risk exposures between blood donors who test positive (cases) for HIV (NAT yield and seropositive), HCV (NAT yield), and/or HBV (NAT yield) to persons who test false positive i.e., are not infected (controls). This case-control study design will yield interview data on risk behaviors among blood donors that will be used to understand predominant risk behaviors associated with HIV, HBV, or HCV infections in United States blood donors. Routes and risks factors for infection acquisition are different for each of these three viral infections but may include male-to-male sex, having multiple heterosexual partners, injection drug use (IDU), exchanging money or drugs for sex, and some medical procedures. The only way to collect information on these risk factors is to directly ask participants to self-disclose these behaviors or exposures.

The results may also lead to the identification of areas of the standard donor health history questionnaire completed at the time of blood donation which would benefit from modification in ways that can decrease risk and improve risk behavior disclosure at the time of donation, or by determining if aspects of the current pre-donation donor questionnaires are inadequate.

The project will inquire about potentially personally identifiable information (PII) as well as risk behaviors. Risk behaviors will be assessed in three or more time-based exposure periods, typically “ever,” “in the last year,” and “in the last three months before the blood donation”. Please see the attachment for the study questionnaire. Donors will be asked to provide their date of birth, educational attainment, ethnicity and race. Of these data elements only date of birth is formally classified as PII by the National Institute of Standards and Technology. The information obtained will not be linked to any other data sources outside of TTIMS. Blood centers collect and must maintain PII, especially for donors who test positive for infections. The information collected will only include data that can be used to report results in broad groups as opposed to individuals. This information is necessary because it may identify that blood centers are not providing educational materials to specific groups of donors in ways that are most effective for donor eligibility assessment. The only way to assess and monitor trends between groups of blood donors is to collect a limited set of PII. Results will be reported in aggregate and never at the individual donor level. By allowing donors to indicate “other” or “mark all that apply” responses, the project provides routes for donors to choose how much PII they are willing to disclose. This information collection will not compel donors to provide any demographic information.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 300 hours annually.

Table 1.--Estimated Annual Reporting Burden					
Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cases and Controls[1]	600	1	600	0.50 (30 minutes)	300

[1] Cases consist of virus-positive donations, and controls represent uninfected donors.

The estimated number of annual respondents is 600. The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. It is estimated that each respondent will spend about 30 minutes (0.50 hours) during recruitment to participate and completing the telephone or in-person interview.

12b. Annualized Cost Burden Estimate

The estimated annualized cost to respondents $7,800.

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Cases and Controls	300	$26	$7,800

[1] average hourly earnings, all employees, private sector; the data is published by the Bureau of Labor Statistics and can be found on their Web site at http://www.bls.gov/webapps/legacy/cesbtab3.htm by checking the boxes marked "Average Hourly Earnings" and "Average Weekly Earnings", then clicking on the "Retrieve Data" button.

The respondent population of United States blood donors represents a wide variety and range of wage rates. The $25.53 per hour wage rate was selected based on Bureau of Labor Statistics reported overall labor force mean hourly earnings average hourly earnings for all employees in the private sector in April 2016. The $25.53 rate was rounded to $26 for this estimate.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government for this information collection is $846,597. This is the cost of the Laboratory and Risk Factor Coordinating Center (LRCC) contract for the TTIMS project.

15. Explanation for Program Changes or Adjustments

FDA has adjusted our burden estimate, which has resulted in a decrease to the currently approved burden of 300 hours. Based on experience with this survey, we decreased the average burden per response from 45 to 30 minutes resulting in a change from the previous 450 hours to 300 total hours which is a decrease of 150 hours. We also have revised the currently approved collection instrument for the collection of information and have included Agency guidance, as described in section 1 of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The schedule for study activities is shown in table below.

Project Time Schedule	
Task	**Date of completion**
Risk Factor Survey Administration and Data Collection begins	1 week after OMB approval
Risk Factor Survey Administration and Data Collection ends	3 years after OMB approval –an extension of OMB approval will be sought
Data Compilation and QC	At monthly intervals after OMB approval
Data Analysis	10 – 14 months after OMB approval, and at 3 month intervals thereafter

Results will be disseminated to the scientific and blood banking community and others through peer-review journal publications. In addition, data requests for presentations by Federal and non-Federal agencies, including the FDA Blood Products Advisory Committee, the HHS Advisory Committee on Blood and Tissue Safety and Availability, the AABB Transfusion-Transmitted Diseases Committee, and the America's Blood Centers Association are expected.

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

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.