Supporting Statement A for

Investigating the Causes of Post Donation Information (PDI): Errors in the Donor Screening Process (NHLBI)

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SUPPORTING STATEMENT

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Blood centers are required to use a health history screening questionnaire to obtain eligibility information for the protection of the donor and recipient prior to blood donation. However, the health history process is known to be error-prone and the reasons for those errors are largely unknown and untested. Donors often fail to report a risk that would have resulted in deferral. This deferral risk may be disclosed at a subsequent donation and is classified as Post Donation Information (PDI). While this deferral risk may be at the next donation event, many examples of PDI are not disclosed nor discovered until several intervening donation events have occurred. The reasons why donors fail to disclose a deferrable history at the time of one donation but subsequently disclose this information at a later time are unidentified. This protocol is designed to ascertain why PDI error events occur. It will be the first study of any kind to address the issue of PDI errors in any systematic fashion. By conducting interviews with donors involved in PDI errors, we will gain important qualitative knowledge about this problem. Information gathered from these interviews will not only elucidate the issue of PDI but will provide insight into donor understanding of the screening process and their feelings about the process and blood donation in general.

Data from the FDA's FY07 Annual Summary on Blood Product Deviation (BPD) Reports[1] show that most PDI information (90%) was known by the donor at the time of

[1] Food and Drug Administration. Center for Biologics Evaluation and Research. Biological Product Deviation Reports-Annual Summary for Fiscal Year 2007.

the index donation (the donation where the deferrable history was known by the donor and not disclosed) but, for unknown reasons, was not provided. Most of the remaining cases of PDI are things not known by the donor at the time of donation but later reported. This might include the subsequent diagnosis of a disease and the donor calls to inform the blood center of this new health information that may pose recipient risk. Most of the remaining BPDs (2,027) related to donor suitability were outright donor screening errors made by the health historians during the screening process and most frequently were related to accepting donors with an overt history that was deferrable. There has been no change in these data since the FDA began publishing them in FY01. The donor suitability system and PDI account for the largest number of BPD reports, but there has been almost no research into why these PDI and donor screening errors occur or what could be done to prevent or reduce their occurrence.

We propose this as an exploratory study that will allow us to better understand the problems and issues related to the health-history screening process and the roles that donors and health-historians play. By gathering these initial data on PDI donors and the reasons for PDI events, we lay the ground work for a possible larger scale PDI donor survey to further examine these issues. This will also allow us to strategize potential interventions as a comprehensive part of a phase two study. Additionally, given the present dearth of information about why these errors occur, we believe this initial study with interviews of PDI and deferred donors will provide meaningful insight on this problem that may be useful in helping reduce the incidence of PDI while also providing publishable data regarding PDI.

The main objectives of the study are:

1. To explore reasons behind errors in the donor screening process when donors initially fail to disclose an accurate and complete health history.
2. To explore PDI donors' knowledge, attitudes, behaviors and beliefs (KABB) about the health history questionnaire and their experience with the screening process and the center.
3. To compare KABB in PDI donors to deferred (but not PDI) donors and accepted donors.

Collecting the proposed information is a vital part of the overall responsibility of the Federal Government and U.S. blood collection centers to ensure the safety and availability of the national blood supply. NHLBI has a Congressional mandate, Sec 421 [285b-3] and 422 [285b-4] to ensure the overall safety of the blood supply (See Attachment 1). An important aspect to this assurance is ongoing research regarding blood donation practices and procedures to ensure the safety of donors while ensuring a blood supply adequate to fulfill the nation's need.

A.2. Purpose and use of information collection

Since 1989, the NHLBI-sponsored Retrovirus Epidemiology Donor Study (REDS) and REDS-II program has conducted epidemiologic, laboratory and survey research in the field of blood safety.

Data collected in this study will be of practical use to the blood banking community and to the Federal Government (See Section A.1.). In addition to the traditional route of peer reviewed scientific publication, previous REDS-I study data were

the subject of numerous requested presentations by Federal and non-Federal agencies, including the FDA Blood Products Advisory Committee, the HHS Advisory committee on Blood Safety and Availability, the AABB Transfusion-Transmitted Diseases Committee, and the Americas Blood Centers Association. We anticipate similar requests for data generated from this study.

A.3. Use of Information Technology and Burden Reduction

Consented study participants will provide responses through telephone interviews conducted by trained personnel (Attachment 4: PDI Study Consent Form). We plan to perform cognitive testing of the discussion guide and study procedures for enrollment. This will provide feedback for reviewing and streamlining study procedures. The discussion guide consist of tried and tested questions from donor health history questionnaire and other REDS surveys. The discussion guide also provides flexibility and skip patterns to avoid having respondents answer unnecessary questions (see Attachment 2 for PDI discussion guide).

A.4. Efforts to Identify Duplication and Use of Similar Information

A literature search shows that this will be the first study of any kind to address the issue of PDI errors in any systematic fashion. This information is not routinely collected by U.S. blood collection centers in the course of their regular donor screening operations.

A.5. Impact on Small Businesses or Other Small Entities

Small businesses or entities are not involved. All respondents are individual blood donors.

A.6. Consequences of Collecting the Information Less Frequently

As mentioned in the earlier sections, study participants will be interviewed once only. Donors who agree to participate will be consented and asked to participate in the phone interview. There is no follow-up involved.

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

The proposed data collection is consistent with 5 CFR 1320.5.

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

The 60-day Federal Register Notice was published on February 23, 2010 in Volume 75, No. 35, pages 8080 - 8081. Two comments were received and responded via email by the Principal Investigator of the study. There has been consultation outside of NHLBI to conceptualize and design the proposed study. The final study design was developed, reviewed, and approved by the REDS-II subcommittee, the REDS-II Steering Committee, and the Observational Study Monitoring Board (OSMB) (See Attachment 5.1 for a complete list of members). The OSMB reviewed the final protocol and provided input and comments (see Attachment 3 for PDI study protocol). Revisions were made to the protocol incorporating the suggestions of the OSMB.

A.9. Explanation of Any Payment or Gifts to Respondents

Once the interview is conducted successfully, each study donor will be mailed a check of $25 as an incentive for participating in the study.

Based on the previous experience conducting similar qualitative interviews that involve sensitive questions, the study investigators believe that providing this incentive will enhance the participation rate. It is also assumed that $25 is an adequate amount of

money to compensate for the study subject's time spent in reviewing study materials, signing and mailing the informed consent form, as well as participating in a half an hour telephone interview.

A.10. Assurance of Confidentiality Provided to Respondents

This data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." Please see Attachment 7 for the memo stating that Privacy Act is applicable to this protocol. Any identifiable information about the participant will be handled as confidentially as possible by the investigators. Their name and address will be kept in a locked file at the blood center. Other study data will have a code number instead of the name. Participant's name will not be used in any published report about this study. To provide additional protection of privacy, Westat and the blood centers have obtained a Certificate of Confidentiality in accordance with Section 301(d) of the Public Health Service Act. This certificate prevents study staff from being able to disclose information that may identify participants by court order or other legal action. This protection lasts forever (even after death) for all study participants.

The contact information will only be used by Westat for the purposes of contacting blood donors for the study interview. At the end of the interview, the interviewer will confirm the mailing address and send a $25 incentive. Westat will destroy all of personal identifying information upon completion of the study and none of this information will be linked to the interview responses.

A.11. Justification for Sensitive Questions

Blood donors in the United States are required by AABB (formerly the American Association of Blood Banks) and Food and Drug Administration to answer specific health and personal history questions and to read educational materials related to the signs and symptoms of HIV, transmission of infection by blood donation, withdrawing from blood donation, and the importance of giving accurate information. Most blood centers in the United States have adopted the Uniform Donor History Questionnaire (UDHQ) as the format for asking or self-administering the health and personal history questions. See Attachment 5.2 for detailed justification for sensitive questions and question by question description and purpose of each question included in the discussion guide. A template of the current UDHQ is available in Attachment 5.3.

PDI is directly related to the questions that every blood donor sees at each donation attempt. PDI is an error in the health history screening process that occurs when a donor gives health or personal information that permitted donation, but subsequently provides information that results in donor deferral. Most frequently, this deferral information was known by the donor at the time of the initial donation, but not disclosed. The reasons for non-disclosure are unclear. While a donor may reveal deferral history at the next donation, many donors continue to give multiple times before the deferrable history is disclosed. Examples of histories that would have resulted in deferral if they had been disclosed include travel to malaria areas, certain medical conditions, medications, men having sex with men, IV drug use and tattoos.

We will be asking donors about the specific question that resulted in their PDI and subsequent deferral. These questions will be no different than those already seen by the

donor during their previous donations and latest donation attempt that resulted in deferral. We will also be asking questions related to their knowledge, attitudes, behaviors and beliefs relative to why the question is asked, if they read deferral and educational materials (Attachment 5.4) related to blood donation, their understanding of these materials and their experiences in the screening process and their interaction with blood center staff. Their responses will be compared with appropriately deferred (not PDI donors) donors who will experience the same type of interview questions and accepted donors. Appropriately deferred and accepted donors have likewise seen the health and personal history questions and educational materials during each and every donation event.

While Attachment 5.4 shows the required questions for donor qualification, we have further broken these questions into five broad categories. These categories of questions include Medical, Blood/Disease Exposure, Travel, High Risk Behavior-Sexual, and High Risk Behavior-Non Sexual. This will facilitate analysis across the three groups of donors and allow us to identify differences based upon the kind of deferral history that is at some point finally disclosed.

A.12. Estimates of Burden Hour Including Annualized Hourly Costs

The annualized cost to respondents is estimated at $1505.52 based on $18 per hour. The respondent population of U.S. blood donors represents a wide variety and range of wage rates. Therefore, the $18.00 per hour wage rate was selected based on reported overall labor force mean hourly earnings in 2009. It is estimated that each respondent will spend about 30 minutes (0.5 burden hours) reading and

understanding the study information material and completing a telephone interview.

Table A.12-1 ESTIMATES OF HOUR BURDEN				
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per response	Annual Hour Burden
Donors initially contacted	408	1	.08	32.6
PDI Donors	60*	1	0.5	30
Deferred Donors	30*	1	0.5	15
Accepted Donors	12*	1	0.5	6
Total	408			83.64

**These respondents are a subgroup of total 408 donors who will be initially contacted to participate in the study.*

Table A.12-2 ANNUALIZED COST TO RESPONDENTS					
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per respondents	Hourly Wage Rate	Respondent Cost
Donors initially contacted	408	1	.08	$18	587.52
PDI Donors	60*	1	0.5	$18	540
Deferred Donors	30*	1	0.5	$18	270
Accepted Donors	12*	1	0.5	$18	108
Total	408				1505.52

**These respondents are a subgroup of total 408 donors who will be initially contacted to participate in the study.*

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

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

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government for the proposed study is estimated to be approximately $ 240,042 (per year).

	Direct and Indirect Costs
Centers	$12,000
Coordinating Center	$192,601
Central Laboratory	NA
Total	**$204,601**

A.15. Explanation for Program Changes or Adjustments

This submission constitutes a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The schedule for study activities is shown in Table A.16.

A.16-1 Project Time Schedule

Task	**Date of completion**
Phone contact made with Eligible Donors	1 week after OMB approval
Study Packet mailed to Eligible Donors	2 weeks after OMB approval
Schedule Interviews	1 month after OMB approval
Complete all Interviews	2-3 months after OMB approval
Data compilation and QC	3 months after OMB approval
Analyses	4 months after OMB approval

Subject to NHLBI approval, data will be disseminated to the scientific and blood banking community and others through peer-review journal publications, and presentations at government (FDA Blood Products Advisory Committee) and professional meetings (AABB).

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

The OMB expiration date will be displayed in the upper-right hand corner of the questionnaire.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification for paperwork reduction act submissions.