

Supporting Statement A for
The effectiveness of donor notification, HIV counseling, and
linkage of HIV positive donors to health care in Brazil

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Project Officer/ICD Contact:

Simone Glynn, MD
Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Two Rockledge Center
Suite 9142
6701 Rockledge Drive
Bethesda, MD 20892
Phone: (301) 435-0065
Fax: (301) 480-0868
Email: glynnsa@nhlbi.nih.gov

TABLE OF CONTENTS

SUPPORTING STATEMENT.....1
Introduction and Summary.....1
A. Justification.....1
A.1. Circumstances Making the Collection of Information Necessary.....1
A.2. Purpose and Use of the Information.....3
A.3. Use of Information Technology and Burden Reduction.....4
A.4. Efforts to Identify Duplication and Use of Similar Information.....5
A.5. Impact on Small Businesses or Other Small Entities.....5
A.6. Consequences of Collecting the Information at a Chosen Frequency.....5
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....6
A.8. Comments in Response to the Federal Register Notice and Efforts to
 Consult Outside Agency.....6
A.9. Explanation of Any Payment or Gifts to Respondents.....6
A.10. Assurance of Confidentiality Provided to Respondents.....6
A.11. Justification for Sensitive Questions.....8
A.12. Estimates of Burden Hours Including Annualized Hourly Costs.....10
A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record.....
 Keepers11
A.14. Annualized Cost to the Federal Government.....11
A.15. Explanation for Program Changes or Adjustments.....12
A.16. Plans for Tabulation and Publication and Project Time Schedule.....12
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....12
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....12

REFERENCES.....13

ATTACHMENTS

- Attachment 1: ACASI Questionnaire English
- Attachment 2: ACASI Questionnaire Informed Consent
- Attachment 3: Supporting Documents
 - 3.1 OSMB members
 - 3.2 ACASI Questionnaire: Description of each item, source, and goal
 - 3.3 Brazil HIV IAC
- Attachment 4: REDSIII Brazil Notification HIV Protocol
- Attachment 5: ACASI Questionnaire Portuguese
- Attachment 6: ACASI Questionnaire Informed Consent Portuguese
- Attachment 7: Invitation to Study Letter – English and Portuguese

SUPPORTING STATEMENT

Introduction and Summary

The prevention of transfusion-associated transmission of HIV is one of the greatest success stories in the fight against the HIV epidemic; however, the job is unfinished. In some middle-and low-income countries, blood transfusion may account for up to 6% of HIV infections (1). Currently, all blood donors who test positive or inconclusive for HIV or other sexually transmitted diseases are notified (donor notification) and requested to follow-up with the blood bank for potential confirmatory testing and referral to specific health services, such as monitoring and treatment. Little is known about the consequences of blood donor notification and subsequent monitoring and counseling on efforts to control the HIV epidemic in the United States and internationally.

This proposed study, “The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in *Brazil*” (The Brazil Notification Study), addresses this significant information gap with three objectives. The first objective formally measures donor notification rates in Brazil. The second objective measures HIV follow-up rates and donor behavior in relation to activities, such as linkage to health care resources and behavioral risk reduction through monitoring and counseling after donor notification. The third objective seeks to find ways to improve the disclosure of HIV risks during donor eligibility assessment at the time of blood donation. We will enroll a cohort of HIV-positive donors to assess these three objectives. Our findings will yield insights into improved methods for donor self-selection and qualification post donation, which will serve to decrease the frequency of higher-risk persons acting as donors. Our findings on improved methods for Brazilian donor notification and linkage to health care services may also be applicable to developed countries, including the US. Results of the Brazil Notification Study will identify how to improve notification and counseling strategies that increase the number of HIV-positive donors seeking prompt medical care. This might ultimately boost strategies to prevent secondary HIV transmission and reduce the risk of transfusion-transmission.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

As noted in the Part 1 Worksheet, under [Title 42](#) › [Chapter 6A](#) › [Subchapter III](#) › [Part C](#) › [Subpart 2](#) › § 285b–1 the Director of the National Heart, Lung and Blood Institute (NHLBI) shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities. The proposed study, “The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil,” (REDS-III HIV case surveillance risk factor study) fits within the NHLBI’s research agenda as described here and in the other supporting documents.

In the US and in Brazil, the safety of the blood supply has been achieved by a

combination of donor self-deferral, the donor selection process, testing for known pathogens, and thoughtful management of donors and blood component inventories by blood centers. None of these are foolproof on their own. However, together they provide layers of safety that protect the blood supply. Donor selection ultimately relies on a relationship of trust between blood donors and blood centers. The collection of donations from donors with undisclosed risk factors may result in increased risk of transfusion-transmitted infection due to the presence of window period infections in which these newly acquired infections may not be detected by available testing methods. Further, even with the adoption of Nucleic Acid Testing (NAT) for HIV; a small risk of HIV transmission remains, due to low-level viremia during the testing window period capable of causing transfusion-transmission, and the possibility of mutated virus strains that could be missed by current testing technologies, including recombinant subtypes (18-19).

When donors test positive for infections, a series of follow-up activities are important including informing the donor of the results. In the United States, for blood donors with positive and/or inconclusive markers for HTLV, Syphilis, Hepatitis B and C, Chagas Disease and other markers, the blood bank sends a letter to the blood donor with the test results information. The letter provides donors with blood center contact information in case the donor needs further information; the letter also suggests that the donor make an appointment with their physician for further analyses and treatment if necessary. Those donors with positive or inconclusive markers for HIV are invited to return to the blood bank for in-person counseling and notification with a trained physician. Unfortunately, blood banks do not follow-up with those donors who do not reach out to the blood center after they receive their letter.

The donor notification procedures used in Brazil are similar to those in the US. Brazilian blood bank regulations establish that blood donors with positive or inconclusive testing markers for HIV, hepatitis B or C, Syphilis, Chagas diseases and HTLV must come back to the blood bank for confirmatory testing and referral to specific health services to confirm the diagnosis and subsequent monitoring and treatment. Specifically, each blood donor with any positive or inconclusive serologic markers receives a letter asking him/her to return to the blood bank for further counseling. That letter does not give any information about test results, but just asks the donor to return as soon as possible.

HIV counseling and testing (HCT) is the entrée to care for infected persons in Brazil and when successful, provides direct and indirect prevention benefits. However, before a blood donor can be referred to a HCT, a donor must come back to the blood center for notification and counseling related to the donation testing results. Approximately 60% of HIV-positive donors in Brazil return for notification (2), but there are no published data showing how many of those donors actually attend the HCT centers for follow up care and treatment. In addition, the 40% who do not return may unknowingly contribute to the transmission of HIV and other infections in the broader community.

HIV positive persons may reduce their risk of transmitting the virus to others through behavior change following HCT, viral load suppression by antiretroviral therapy (ART), and referrals to other preventive and social services (3-7). The evidence of the impact of HIV counseling and testing on subsequent high-risk sexual behavior has been mixed. While some studies have found significant declines in the reporting of multiple sex partners and unprotected sex, other studies have found limited or negative effects of testing on behavior change (8, 9).

This proposed Brazil Notification Study seeks to gather formal detailed data about the donor notification process and the consequences of the notification and post-notification processes on HIV positive blood donor behavior. The findings from this project will enhance notification of blood donors about infectious disease markers.

A.2. Purpose and Use of the Information

Since 1989, the NHLBI-sponsored REDS program as well as its second phase, REDS-II, and the current REDS-III, have conducted epidemiologic, laboratory and survey research in the field of blood safety. The goal of the REDS-III International Component is to conduct epidemiologic, laboratory, and survey research in blood banking and transfusion medicine in selected resource-limited countries in regions seriously affected by the AIDS epidemic to help increase the safety and availability of blood for transfusion. To achieve those goals, the REDS-III Brazil program and particularly the objectives of this study are as follows: a) assessment of blood donors return rate for notification and the association with each blood-borne infection tested by the four Brazil blood centers (Hemorio, Rio de Janeiro; Hemope, Recife; Hemominas, Minas Gerais; and, Fundação Pró-Sangue, São Paulo); b) assessment of changes in risk behaviors among HIV-positive donors who participated in a prior REDS-II HIV study or have enrolled in the ongoing REDS-III HIV study; c) collection of data that may provide insight on how to improve the disclosure of HIV risks during the donor screening process; and, d) to gain a better understanding of the motivating factors that lead higher risk persons to donate blood. Exploring blood donor behaviors and attitudes, including sexual practices, disclosure of HIV positivity to partners, the length of time between the blood bank's notification and seeking appropriate health care will help to elucidate important patterns related to HIV transmission. These data will help to develop strategies to improve the notification process and care which ultimately may improve blood safety.

Focused on these REDS-III objectives, the Brazil HIV Notification study team proposes to enroll all former blood donors who participated in the REDS-II HIV case-control study (OMB 0925- 0597, expired on February 29, 2012) and those enrolled during the REDS-III HIV case surveillance risk factor study (OMB 0925-0597, expiration date, July 31, 2015), between 2012 and 2014. Donor enrollees at any of the four blood centers participating in these studies completed an audio computer-assisted structured interview (ACASI) that elicited responses on demographics, risk factors/behaviors, and HIV knowledge. At the same time, a blood sample was drawn and tested for HIV genotype and drug resistance. In addition, recent infection status was determined using detuned antibody testing of samples from the original blood donation. All enrolled participants received counseling by a blood bank physician and were referred to HIV counseling and testing centers (HCT).

New information gathered from these enrollees will serve the three aims proposed for this study. The first aim of this study will be to analyze the actual percentage of blood donors who are successfully notified of their infection testing results. In this aim, we will expand the notification focus to include all infections that blood centers in Brazil test for because differences in rates of notification by type of infection are unknown. The second aim will assess the effectiveness of HIV notification and counseling. HIV-positive donors will be interviewed to evaluate their follow-up activities with regard to HIV infection treatment and infection transmission prevention behavior after notification by the blood center. This will be accomplished using a new audio computer-assisted structured

interview (ACASI) (See Attachment 1, Brazil HIV Follow up ACASI Survey). The third aim will consist of asking HIV-positive blood donors about ways to improve the disclosure of HIV risks during donor eligibility assessment to better understand the motivating factors that drive higher risk persons to donate blood.

Because our study will build off the routine blood donor procedures in four large blood banks in Brazil, it may lead to more informed conversations around and possible changes in donor screening, notification and counseling policies in Latin America. Results of these aims may also help to better integrate blood centers within the context of broader HIV testing, counseling and treatment sites in Brazil. Similarly, in the US little is known about donor behavior after notification of testing results by blood centers. The results from this study can be used to develop insights and hypotheses focused on developing improved strategies for notification and counseling of HIV-positive (or hepatitis C or B-positive) donors in the U.S.

In addition to the traditional route of scientific dissemination through peer reviewed scientific publication, previous REDS and REDS-II 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 (ABC). We anticipate similar requests for results generated from this study. Data collected in this proposed notification and HIV follow-up study of donors will be of practical use to the blood banking and infectious disease communities in the US and internationally.

A.3. Use of Information Technology and Burden Reduction

A detailed questionnaire on the topics of access to health care and risk behaviors will be completed (See *Attachment 1*) at four (4) Brazil blood centers in the cities of Recife, Belo Horizonte, São Paulo and Rio de Janeiro.

These interviews will be completed using the computers that were purchased for the REDS-III Brazil study (Dengue Virus Incidence and Prevalence in Brazilian Donors and Recipients, Rates and Correlates of Transfusion-Transmission, and Clinical Outcomes of Infection in Recipients, CE 2011-11-002). Using these non-HIV study computers will ensure that the research assistant initiates the correct interview. Private locations in each blood center will be made available for the participant to complete the ACASI. The administration of the questionnaire will be performed using self-administered ACASI on computer to maximize reporting of stigmatizing or socially sensitive behaviors. This format has been proven to encourage risk disclosure and enhance participation in the previous REDS-II and current REDS-III HIV case surveillance studies.

A research assistant or nurse will direct the participant to a private room where the ACASI computer (with earphones to assure privacy) is located at each blood center. The study subject will be shown how to use the computer to complete the interview by entering basic demographic data with the help of the research staff, but will be given privacy to complete the rest of the questionnaire. A Privacy Impact Assessment is in process for the computer systems. The research assistant will remain available to answer questions and provide help as necessary. We chose ACASI to maximize reporting of stigmatized risk behaviors and to streamline the interview. Gate questions and skip patterns assure that only necessary questions are asked. The ACASI format also uses

electronic data capture, which reduces data entry errors. The ACASI program has proven successful during the previous HIV studies conducted in Brazil. The young Brazilian subjects adapted easily to the touch-screen computer interview, while older or less literate donors relied more heavily on the audio component and/or assistance from the research assistant and/or nurse. Additionally, to support our objectives we will access the responses from the two previous ACASI questionnaires, the original HIV-positive case interviews from the REDS-II case control and the REDS-III HIV risk factor and molecular case surveillance studies.

Respondents will continue to be assured of the privacy of their responses to the extent permitted by law. Use of a Subject ID on the questionnaire allows for tracking of survey responses without entering any personally identifying information into the study database. The link between the Subject ID number and the identity of the donor is only maintained by each blood center. This link is maintained so that HIV-positive participants can be re-contacted with their genotyping and drug resistance test results or in a situation where the donor wishes to withdraw from the study. The US-based Data Coordinating Center (DCC) will not have access to any personal identifying information.

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

This study seeks to provide critical supplemental information to the HIV-positive donor (case) surveillance risk factor information being collected in the current REDS-III HIV risk factor study previously described (OMB 0925-0597, expiration date, July 31, 2015), and the REDS-II HIV case-control study (OMB 0925- 0597 expired on February 29, 2012). The REDS-II and REDS-III studies provide a well-defined cohort of HIV positive donors. Based on investigating what actually occurs in these blood centers, this study will provide an understanding of behavioral patterns pre and post notification, processes for referral to proper HIV disease care, and will provide a clearer picture of the gaps in the transitioning of HIV positive individuals from blood centers to health care clinics. The assessment of the behavior of blood donors with respect to notification and referral to HCT centers should directly, and affirmatively, affect the epidemiology and spread of HIV in Brazil.

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 at a Chosen Frequency

Questionnaires will be administered only once to all participants in an ACASI format on a computer. The content domains of this interview include; what has happened to the donor since being notified of his/her HIV infection status at the blood center, questions related to access to health care and treatment, risk reduction after HIV notification, HIV status disclosure to sexual partners, family and friends, perceptions of stigma and prejudice, and enhancements that the donor thinks can be made to increase HIV risk disclosure during the donor eligibility assessment. Data collected from each respondent during this interview are essential to understanding health care seeking

behavior in the study population and the interview itself constitutes a minimal level of burden on the respondents.

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

As noted in the Part II Worksheet, the 60-day Federal Register Notice was published in Volume 80 page 18853 on April 8, 2015. No public comments were received during that public comment period. There was consultation outside of NHLBI to conceptualize and design the study. The final study design was developed, reviewed, and approved by the REDS-III Brazil Steering Committee, REDS-III Executive Committee and the Observational Study Monitoring Board (OSMB). The OSMB reviewed the final protocol and provided input and comments. Revisions were made to the Informed Consent document participants will sign to address OSMB comments asking the study investigators to clearly state that strict privacy safeguards will be maintained throughout the study. The revised protocol has been reviewed and approved by the REDS-III Brazil Steering Committee and the REDS-III International Advisory Committee (See Attachment 3.3 for a complete list of members) and will be monitored by the REDS-III OSMB (See Attachment 3.1 for a complete list of members).

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

The reimbursement amount offered to study participants will be US\$35 (R\$75 in Brazil currency), considering the following issues. First, since a time period as long as 7 years may have elapsed since some of these donors participated in the HIV case-control study under REDS-II (OMB 0925- 0597, expired on February 29, 2012), a higher participation reimbursement is planned that better reflects current Brazilian wage structures. Second, US\$ 8 was used in REDS-II HIV case-control study and R\$15 is currently being used in the REDS-III HIV case surveillance risk factor study (OMB Approval Number: 0925–0597, Expiration Date: July 31, 2015). This proposed new study depends on successfully getting these same participants enrolled again. There is no alternate study population we can use, so using the planned reimbursement structure will acknowledge participants for taking time away from other activities to participate in this study. Third, a recent non-REDS R01 study conducted in one of the REDS-III blood centers in Brazil offered a higher reimbursement (US\$50), and was successful at achieving a return rate of 85% in a subsequent qualitative study. Fourth, the budget impact is relatively small.

A.10. Assurance of Confidentiality Provided to Respondents

All respondents will be assured of the actions taken by the blood centers, study staff in Brazil and collaborators in the US to safeguard participant privacy. Procedures

planned for this study are being successfully implemented on the current REDS-III HIV case surveillance risk factor study and they are described here. Respondents will be shown how to use the computer to complete the interview by entering basic demographic data with the help of the research assistant or nurse, but will be given privacy to complete the rest of the questionnaire. Respondents will be assured of the privacy of their responses to the extent permitted by law. To assist respondents, trained counselors will be on site during and after the ACASI interviews should participants want additional counseling. Use of a Subject ID on the ACASI questionnaire will allow for tracking of survey responses without entering identifying information into the study database. The link between the Subject ID number and the identity of the donor is only maintained by the blood centers. This link is maintained so that HIV positive participants can be identified by study staff in Brazil in a situation where the donor wishes to withdraw from the study. The US-based Data Coordinating Center (DCC) and study investigators will not have access to any respondent identifying information. In addition, a special data security plan has been developed for this study with enhanced effort to protect participant privacy.

The data security plan has been specially designed to assure privacy of the research conducted by the study team before, during, and after the study (details can be found in *Appendix 1 of Attachment 4*). For instance, participant names and other personally identifying information will be used to conduct this study and there will be written, signed consent and identifying information from donors that is temporarily linkable to the laboratory results, routine donation records and our study specific-questionnaire. We will take several steps to minimize the possibility of inadvertent disclosure of the identity and information of participants. First, data are tracked and linked with a donor registration number (RID) created at the time a person first presents for donation. For our study, none of the datasets created for analysis and transferred to the US will contain the participants name or contact information, rather the RID will be used to link the donation history, health and risk screening data, laboratory results and study specific questionnaires entered into the study database. To increase the epidemiological power of the study, we will get participants' consent to obtain HIV infection status information, such as viral load and CD4/CD8 counts (Aim 2), which have been captured in the Brazilian Ministry of Health (MOH) National HIV treatment and progression databases (SI-CTA). In order to conduct the linkage to the Brazilian SI-CTA databases, personal identifiers are required. The research staff that conducts this portion of the study will be based solely in Brazil and will have previous experience maintaining appropriate privacy protections. These will include only working on password protected workstations that require individual usernames and passwords. Any electronic transfer of information with the Brazil MOH will be conducted using encrypted files only accessible by passwords that will not accompany the datasets during transmission. A single person (TBN) from each site will work with the Brazil MOH databases to obtain the data in accord with all required ethical committee approvals and MOH security requirements. The HIV disease monitoring data will then be entered into the research databases using the RID and study number as the unique identifiers. The written consent forms will not contain the RID. These numbers will be stored separately from study data in locked filing cabinets at the blood banks. Once data collection is complete and all data verified, the RID will be permanently removed from the study database thus eliminating any possibility of re-identifying participants and any information on individuals in our study. Only non-linkable study identification numbers will be used in the research databases. No

names or individual identifiers will be used in any reports of publications resulting from this study.

A.11. Justification for Sensitive Questions

The first two sections (A and B) of the ACASI contain questions are not considered sensitive, such as study administrative information and participant demographics. Note that the race categories asked of respondents in the questionnaire are consistent with the Federal Government of Brazil Census (IBGE) categories.

http://www.ibge.gov.br/home/estatistica/populacao/caracteristicas_raciais/default_raciais.shtm.

Special attention has been devoted to the wording of potentially sensitive questions in subsequent sections with the objective of asking content in a straightforward and non-judgmental manner. Please see *Attachment 3.2* for a detailed justification for each question.

Section C. In Brazil, there is no countrywide system, such as a deferred donor registry, to prevent a donor from attempting to donate at another blood center. A person at risk for HIV infection might donate blood at many blood banks and these questions will capture information on a donor donating at multiple locations. Section C, previous donation and HIV testing in the survey instrument, comprises questions designed to determine among HIV positive donors, their level of effort and intention to get HIV testing through blood donation (test seeking behavior) or at alternative testing sites, such as HCTs, after they learned about their HIV status. Among those high risk individuals, perceptions/confidence and testing frequency for HIV at the blood bank and/or elsewhere will be elicited. Blood bank testing may be more attractive to people seeking highly sensitive HIV testing, particularly with the implementation of nucleic acid testing (NAT) for HIV and HCV in Brazil blood banks—in contrast to HCTs that are still not performing NAT. Dissatisfaction with alternative testing sites has been described as a motivation for individuals testing at blood banks. Identifying factors that contribute or restrain higher risk individuals from seeking HIV testing at blood banks will help in the development of public health strategies, directing higher risk individuals toward HCTs instead.

The sections related to sexual history (Section D); sexual behavior and sexual partners' risks (Section E) will give an overview of participants' current and past sexual life style. Sexual history, including self-declared sexual orientation, age of sexual debut; number of sexual partners during the lifetime, and current or past physical and sexual abuse may all be related to test seeking behavior and non-disclosure of risk during donation. Changes in condom use, men who have sex with men (MSM) behavior, and the risk factors the respondents' sexual partners may have will provide a better understanding of risk reduction after HIV results notification. The sexual history responses will allow us to determine the most prevalent patterns of sexual behavior for HIV-positive blood donors in Brazil, whether these patterns may or may not be correlated with risk behavior changes, and with specific serologic markers and routes of transmission. Inquiring about the same risk behaviors as those covered during the previous REDS-II and REDS-III Brazil HIV studies is critical so that we can compare previous responses to responses from this study to demonstrate the degree of behavioral risk reduction (if any).

In many countries, including Brazil, the path of HIV spread is by both

homosexual and heterosexual transmission. The social matrix section (Section F) is designed to capture detailed sexual information in the 12 months before participating in this study. Reasons for focusing on this period of time include that: a) in general, persons tend to maintain a standard pattern of sexual behavior in their lifetime (MSM, bisexual, heterosexual), and recent sexual activity after HIV notification is of greatest interest for this study, and b) recent specific sexual practices are relevant to identify if higher risk behaviors for HIV transmission are still occurring. Responses from different partners will be combined to determine the frequency that a participant has engaged in higher risk sexual behaviors after notification. We also intend to correlate, in this very well characterized HIV population, risk reduction after the HIV notification and social interaction, including behaviors that could further spread HIV. Answers to these questions will guide future efforts to develop donor health history questions in Brazil (and potentially elsewhere) that can better exclude donors with higher risk.

The medical history section (Section G) will capture information about medical care after the participant learned about his/her HIV status. Questions about current or past anti-retroviral therapy (ART) will be correlated with CD4 and CD8 counts. In addition, questions about blood transfusion and surgery may provide information about the immune dysfunction as HIV infected patients are more susceptible to postoperative adverse events that include sepsis. Moreover, HIV-infected individuals have a higher risk of developing infectious complications after surgery, even after minor procedures (20, 21).

The section on general activities or exposures (Section H) will obtain data related to rare risk factors for HIV infection and includes questions related to tattoos, acupuncture treatment, time spent in jail, prison, or a detention center, body piercings as well as pedicure and manicure treatments at a salon or barber shop. All are routes where exposure to the participant's blood could lead to further onward HIV transmission.

The counseling and notification questions (Section I) will be used to ascertain when and where the participant first learned about their HIV status and whether it occurred before or after the blood donation. To the best of our knowledge questions about participant's confidence in the physician's skills, the physician's relevance to the participant's decision in seeking health care, and how long it took for the participant to seek health care have never been assessed in a former blood donor population. These questions will provide highly relevant information on health seeking behavior and access to care.

Section J includes questions on the impact of the HIV results to the participant's life and social context, HIV status disclosure to close personal contacts and other people, and discrimination and stigma/prejudice. HIV/AIDS related stigmas are invoked as a persistent problem in any discussion about effective responses to the HIV epidemic. In addition to altering the familial, social, and economic livelihoods of individuals, HIV/AIDS-related stigmas are cited as major barriers to accessing prevention, care, and treatment services in non-blood donor populations. Prejudice/stigma can create a substantial barrier to care seeking and it is unknown if blood donors in Brazil are concerned about these issues.

In awareness of the possible sensitive nature of the content of the questions, the following steps will be taken to ensure the privacy of respondents even though personal identifiable information is not collected on the study forms:

- The questionnaire is being administered using an ACASI program. The purpose

of using a self-administered instrument is to ensure privacy to answer questions as honestly as possible and so that potentially stigmatizing behaviors will be reported as honestly as possible without fear or concern that an interviewer would stand in judgment.

- All data will be stored in a secure location, accessible only to authorized study personnel. In addition, due to the sensitive nature of the study, an in-country “Data Security Plan” as detailed in the study protocol has been developed for the four blood sites in Brazil with the objective to reduce the risk of release of personal or sensitive information related to the study population.
- Participants are advised of the voluntary nature of their participation in the study and of the steps taken to ensure the privacy of the information collected. See Informed Consent Document in *Attachment 2*. Participants may request to be de-enrolled from the study at any time during the period that fieldwork is being conducted.

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

The annualized cost to respondents is estimated at \$1,490 based on \$6.50 per hour. It is estimated that each respondent will spend about 50 minutes including administration of the informed consent form (10 minutes) and questionnaire completion (40 minutes). Since we will be working with a subset of enrollees of the OMB approved Brazilian Study that is currently in the field “Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil”, OMB Approval Number: 0925–0597, Expiration Date: July 31, 2015, we are using those same wage rate calculations. (The Brazilian minimum wage translates to approximately \$1.67/hour. Through previous research, the Brazilian blood banks have learned that the majority of their blood donors work in jobs categorized by the Brazilian census as “Technical” positions. According to the census, these “Technical” workers make between \$5 and \$8/hour. For the purpose of this study, we have taken the mean of these salaries, \$6.50/hour, to calculate an estimated cost of participation.)

A.12.1 – ANNUALIZED BURDEN HOURS TO RESPONDENTS

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response	Estimated Total Annual Burden Hours Requested
ACASI Questionnaire Informed Consent	Adults	275	1	10/60	46
ACASI Questionnaire	Adults	275	1	40/60	183

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Respondent	Hourly Wage Rate*	Respondent Cost – all respondents
ACASI Questionnaire Informed Consent	Adults	275	1	10/60	\$6.50	\$298
ACASI Questionnaire	Adults	275	1	40/60	\$6.50	\$1,192

*http://www.bc.edu/content/dam/files/research_sites/agingandwork/pdf/publications/MTG_Brazil_Employee.pdf

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 \$131,724 for activities in Brazil.

Item	Salary	Fringe Rate (%)	% Effort	Annualized Data Collection Cost
NIH Project Oversight Officer - GS15-10	157,100	20	1.5	2,357
1 in-house contractor staff (RTI Staff)	141,296	39	2.6	3,674
6 of field contractor staff	39,648	0	156	61,851
Operational Costs for Data Collection Activities – Printing, equipment, overhead, respondent reimbursement,, non-labor				48,481
Other Contractual costs for data collection, non-labor				0
Travel costs associated with data collection and study launch				5,736
Other costs, non-labor				9,625
Total				131,724

A.15. Explanation for Program Changes or Adjustments

This is a new collection request.

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

The schedule for study activities

Activity	Time Schedule
Initiate Study Recruitment Activities	Immediately following OMB approval
Participant Enrollment and Data Collection (1 year)*	Immediately after OMB approval.
Data Management and Analysis	Ongoing through March 14, 2017

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

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 statement of OMB Form 83-I.

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