

**Supporting Statement A for
Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in
Brazil**

OMB Number: 0925-0597

Extension without Change

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SUPPORTING STATEMENT

Introduction and Summary

This Study is a request for extension without change of OMB Number: 0925-0597 expiration date, July 31, 2015. Establishing and monitoring viral prevalence and incidence rates, and identifying risk behaviors for human immunodeficiency virus (HIV) incidence among donors are critical steps to assessing and reducing the risk of HIV transmission through blood transfusion. Identifying donation from donors with recent HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the blood donor population and hence most likely to "break-through" routine screening measures (i.e., peri-seroconversion, window period donations). In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of recently acquired HIV infections in blood donors enables documentation of the rates of primary transmission of anti-viral drug resistant strains in the community, and serves a public health role in identifying new HIV positive persons who are candidates for anti-retroviral treatment. The current protocol that is approved by OMB, which expires on July 31, 2015, includes both a prospective surveillance and a case study designed to enroll eligible HIV seropositives detected at four participating blood centers in Brazil.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

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, “Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil”, fits within the NHLBI’s research agenda as described here and in the other supporting documents. Defining prevalence and incidence rates in blood donors and residual risk of HIV transmission by transfusions in Brazil may lead to new blood safety initiatives in Brazil. The data obtained from this previously approved study can be used to project the yield, safety impact and cost effectiveness of implementing enhanced testing strategies such as nucleic acid testing (NAT). Determination of HIV risk factors in donors will support policy discussions over strategies to recruit the safest possible donors in Brazil, and will also yield significant information for HIV surveillance in Brazil when combined with prevalence and incidence data derived from general populations and high risk surveillance studies. The identification of incident HIV infections allows for clinical identification of recently transmitted strains of the virus in donor settings in the different cities of Brazil. This surveillance will monitor the trafficking of non-B HIV subtypes and rates of transmission of drug resistant viral strains in low risk blood donors that can be compared with data from similar studies in high risk populations. Monitoring drug resistance strains is extremely important in a country that

provides free antiretroviral (ARV) therapy for HIV infected individuals, many of whom have little education and modest resources, making compliance with drug regimens and hence the potential for development of drug resistant strains of HIV a serious problem.

Given the initiation of NAT testing for HIV (and HCV) in Brazil, it will be important to continue to collect molecular surveillance and risk factor data on HIV infections. Such data will be especially useful for interpreting the findings of HIV NAT testing in Brazil, where test seeking at blood banks is already a concern. Even with the implementation of NAT the residual risk of HIV infection is likely to remain substantially higher than that in the USA. Additional measures towards safe donor recruitment and deferral continue to be essential in further reducing the risk of transfusion-transmitted HIV infection. The continuation of these important HIV activities will directly build upon the capacities established at all 4 blood centers during participation in the previous phase of the study. The results from this study can be used to develop blood safety strategies for countries where blood transfusion remains an ongoing risk factor for the spread of HIV infections. Even for countries such as the U.S and Germany, where the risk of HIV among blood donors is very low^{1,2} the threat associated with NAT failure³ exists and hence the risk of transfusion transmission remains. Thus, even in these settings, results of this study will be pertinent.

The findings from this project will also complement similarly structured monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the US and other funded international REDS-III sites (South Africa and China), thus allowing direct comparisons of these parameters on a global level.

A.2. Purpose and use of the information

Since 1989, the NHLBI-sponsored Retrovirus Epidemiology Donor Study (REDS) program as well as its extended version, REDS-II, and the current Recipient Epidemiology and Donor Evaluation Study (REDS-III), have conducted epidemiologic, laboratory and survey research in the field of blood safety. The goal of the REDS-III Brazil International Program is to enhance the safety and effectiveness of blood banking and transfusion medicine practices in Brazil by performing laboratory, survey, and epidemiological research on specific topics. The specific objectives are to 1) assess and monitor the prevalence and incidence of HIV-1, HIV-2, and other existing as well as newly discovered or emerging infectious agents that pose a threat to blood safety, 2) assess risks of transfusion-transmitted infections, 3) assess the impact of existing and new blood donor screening methodologies on blood safety and availability, 4) evaluate characteristics and behaviors of blood donors including risk factors for acquiring HIV and other blood-borne infections, 5) evaluate the donation process for ways to improve the safety and adequacy of the blood supply, and reduce infectious disease burden, 6) characterize the genotype of recently infected donors for purpose of blood safety, and 7) establish the rates of primary transmission of anti-viral drug resistant strains in the community and identify new HIV infections for anti-retroviral treatment.

The study team proposes to continue the current OMB-approved protocol (OMB Number: 0925-0597 expiration date, July 31, 2015) to enroll all eligible HIV-positive donors who will be identified at the same four blood centers: Sao Paulo, Recife, Rio de Janeiro and Belo Horizonte, and analyze molecular variants and their correlation with risk behavior and HIV treatment. Since December 2012 up to the time of this report, the

study has enrolled 223 HIV-positive donors (51 at Hemorio-Rio de Janeiro, 38 at Hemominas-Minas Gerais, 67 at Hemope-Pernambuco and 67 at Fundacao Pro-Sangue-Sao Paulo) with a target enrollment of 500 by 2017. It is important to continue the study and enroll more HIV infected donors to inform trend analyses. It is worth noting that Brazil is the first developing country to implement early treatment initiation for all individuals living with HIV/AIDS irrespective of CD4 count; this new universal treatment policy went into effect in 2014⁴. Preliminary evaluation of data has shown that respondent donors are completing the entire questionnaire including information about their risk behaviors. Each week the centers at Sao Paulo, Recife and Rio securely electronically transfer their completed questionnaires to the center at Hemominas. REDS-III staff performs careful data quality checks and organize the files before securely transmitting them to the US Data Coordinating Center, Research Triangle Institute (RTI). Molecular genotype and resistance testing is performed on enrollment samples from the HIV infected donors at all centers in Dr. Sabino's lab, which is very experienced at HIV PCR, sequencing and phylogenetic analyses. Current study participants are already returning to the sites to obtain their HIV genotyping results. In addition, Limiting Antigen Avidity (LAg Avidity) testing is conducted on HIV antibody-positive samples to evaluate whether the HIV infection was recently versus more remotely acquired. Since these LAg Avidity test reagents are not available in Brazil, samples are shipped to the REDS-III central laboratory (BSRI) in batches for testing. These test results are not provided back to each participant because those results do not have any practical implications for HIV treatment.

Findings from this study will be compared to trends in prevalence, incidence, and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broader and more effective monitoring of the HIV epidemic in Brazil, as well as assessment of the impact of donor selection criteria on these parameters. We also propose to continue to examine trends in risk behaviors by comparing the data previously collected to the data we plan to collect for the next three year period.

A.3. Use of Information Technology and Burden Reduction

A detailed HIV risk factor questionnaire will continue to be administered to all HIV-positive donor subjects (See Attachment 1), at 4 Brazilian sites (Recife, Belo Horizonte, Sao Paulo and Rio de Janeiro). The administration of the questionnaire will be performed using a self-administered audio computer-assisted self-interview (ACASI) on a computer in order to maximize reporting of stigmatizing or socially sensitive behaviors. A research assistant or nurse will direct the participant to a private room where the ACASI computer (including earphones to be able to listen to the questions privately) 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. The research assistant or nurse 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 (built in skip patterns depending on initial responses so that donors are only prompted to answer questions about the details of a specific risk factor if they report having the risk). The ACASI format also uses electronic data capture which

reduces data entry errors. The ACASI program has demonstrated very good performance during the current, first phase of the study. The young Brazilian subjects adapted easily to the computer interview, while older or illiterate donors relied more heavily on the audio component and/or assistance from the research assistant and/or nurse. The questionnaire is based upon an instrument previously utilized and validated by the US Centers for Disease Control and Prevention (CDC) in its HIV surveillance at U.S. blood banks with modifications appropriate to the Brazilian setting.

Donors will continue to be assured of the privacy of their responses. Use of a Subject ID on the questionnaire will allow 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 the blood centers. This link is maintained so that HIV-positive participants can be re-contacted with their genotyping and drug resistance test results or in a case where the donor wishes to withdraw from the study. The US-based Coordinating Center (CC) will not have access to any donor identifying information.

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

This detailed risk factor information is not routinely collected by Brazilian blood collection centers in the course of their regular or routine donor screening operations, or in a consistent manner across blood centers during routine notification of testing results. Although several studies have been conducted in this area, including the current, first phase of this study, there are nevertheless no adequate data related to the blood donor community, especially in view of the evolving nature of the HIV epidemic in the population and the initiation of NAT testing of blood donations for HIV (and HCV). Blood banks can play an important role in this effort due to HIV testing of large numbers of a young, otherwise healthy population. Regarding clinical relevance of the proposed research, the Brazilian public health authorities have been responsive to the HIV epidemic, with prevention campaigns, provision of condoms, alternative testing sites, and most notably, the implementation of universal access to anti-retroviral treatment (ART)⁵

In 2004, Brazilian policies were changed to allow men who have sex with men (MSM) to donate blood if the last sexual intercourse occurred at least 12 months before the blood donation. The HIV prevalence in Brazil is 10 times higher than in the US. The adoption of NAT is occurring at this time. Therefore there remains a longer infectious window period in Brazil and substantially greater residual risk of transfusion-associated transmission of HIV than in the U.S.^{6,7} and Europe⁸ A recent REDS-II publication in *Transfusion*⁹ showed that even with the implementation of NAT, the risk of residual HIV in Brazil will remain higher than it was in the U.S. prior to NAT screening^{7,10} The continuation of this study at 4 blood centers in Brazil during the next 3-year period of the REDS-III program will enhance the validity and interpretation of the trends in HIV prevalence and incidence observed during the current, continued first phase of this study; further, the continuation of this study will provide a better understanding of the observed epidemiological patterns and help inform guidelines for evaluating changes in HIV. In addition, monitoring HIV viral subtypes and drug resistance patterns, and identifying risk behaviors for incident HIV infections among donors (NAT yield donors and recent seroconverters) are critical steps to assessing and reducing risk of HIV transmission through transfusion. Besides, characterizing genotypes of recently infected donors for purposes of blood safety, and molecular surveillance of HIV infections in blood donors

enables documentation of the rates of primary transmission of anti-viral drug resistant strains in the community, and serves a public health role in identifying new HIV infections for anti-retroviral treatment. Moreover, we will also focus on the following objectives: to observe evidence for changes (declining or increasing) on HIV prevalence and incidence in selected sites and to explore the reasons for the changing patterns, in particular, the role of behavioral changes.

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 subjects in an ACASI format on a computer. The content of this interview includes respondent demographics, history of previous donation and HIV testing, incentives and motivations for donating, sexual history, risks related to sexual partners, alcohol and drug use, medical history, other potential risk factors, work place exposures, and treatment. In addition to blood saved from their index blood donation, 30 ml of blood will be drawn at the time of the enrollment and interview. Data collected from each respondent during this interview are essential to understanding the characteristics of blood donations from the study population; 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

The 60-day Federal Register Notice was published on December 31, 2014 on page 78876, Vol. 79. No public comments were received during that public comment period. There was consultation outside of NHLBI to conceptualize and design the current, first phase of the study. The final study design was developed, reviewed, and approved by the REDS-III subcommittee, the REDS-III Steering Committee, and the Observational Study Monitoring Board (OSMB), and OMB. The proposed continuation of the study for the next phase has been reviewed and approved by the REDS-III Brazil Steering Committee and the REDS-III International Advisory Committee (IAC) (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 project will continue to pay the same amount of R\$15.00 (~\$USD 8.00) to reimburse participants for transportation expenses to and from the study center.

A.10. Assurance of Confidentiality Provided to Respondents

All respondents will be assured of the actions taken to safeguard their privacy and all efforts will be made to secure the privacy of respondent donors to the extent permitted by law. They 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. Use of a Subject ID on the 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 re-contacted with their genotyping and drug resistance test results or in a case where the donor wishes to withdraw from the study. The Coordinating Center (CC) will not have access to any donor identifying information.

A.11. Justification for Sensitive Questions

Special attention has been devoted to carefully designing potentially sensitive questions in a straightforward and non-judgmental way. In Brazil, there is no country-wide 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. To assess a donor's level of altruism by determining if the donor exhibits altruistic behaviors in their daily life, we want to correlate their daily behavioral answers to assess how much of a factor altruism is when donating blood. It is already known that donors will give a socially acceptable response rather than the real reason to donate when asked directly about blood donation. There is a major difference between asking a donor whether altruism is a motivation factor and measuring the degree to which donors report engaging in other altruistic behaviours. The survey instrument is comprised of questions designed to determine the donor's intention to get HIV testing through blood donation (test seeking). Blood bank testing may be attractive to people seeking HIV testing, particularly with advent of HIV NAT use in Brazil blood banks. We intend to ascertain donor's perceptions/confidence related to the HIV testing performed by the blood bank as well as whether this blood testing was a contributing factor in donating. Sexual lifestyle, including the number of sexual partners during the lifetime, increases the odds of having a sexually transmitted disease, as well as its spread. The sexual history responses will allow us to determine the most prevalent sexual patterns for the Brazilian blood donors and whether this pattern may or may not be correlated with specific serologic markers. Note that the race categories asked of respondents in the questionnaire are consistent with the Federal Government of Brazil Census categories (IBGE). http://www.ibge.gov.br/home/estatistica/populacao/caracteristicas_raciais/default_raciais.shtm

In many countries including Brazil, the path of HIV spread has moved from homosexual to heterosexual transmission. However this pattern has not been clearly demonstrated in blood donors. A better understanding of sexual risk factors for HIV may allow us to build more accurate questions at the time of blood donation to improve the donor qualification process. It may also help us to avoid potential discrimination and unnecessary loss of donors if the patterns of HIV transmission are not shown to be

associated with sexual activity. The social matrix section is designed to capture detailed sexual information for up to 5 sexual partners in the 12 months before the last blood donation. Reasons for focusing on this period of time include that: most blood borne disease cases and sexually transmitted disease cases can be diagnosed within 12 months of exposure; in Brazil, having 6 or more sexual partners is the current number of partners leading to deferral for multiple sexual partners; and, in general, persons tend to maintain a standard pattern of sexual behavior in their lifetime (MSM, bisexual, heterosexual) as well as specific sexual practices that are relevant to identify higher risk behaviors for HIV transmission. We assume, therefore, that asking about more than the last 5 sexual partners will not provide significant valuable supplemental information. Responses from different partners will be combined to determine the frequency that a donor has engaged in higher risk sexual behaviors. The individual responses are less important than the combined results across all partners that can be used to determine if specific sexual practices are associated with testing positive for HIV. We also intend to correlate the HIV incidence and prevalence among repeat and first time blood donors. These questions will guide future efforts to develop donor health history questions that will exclude donors with high risk.

The section on alcohol and drug use was included to evaluate the influence of social lifestyle in terms of alcohol and drug use. Use of mood altering substances may be associated with the risk of HIV acquisition. However, this association has not been clearly demonstrated in Brazilian blood donors. We also intend to evaluate whether specific serologic markers are related to riskier behaviors or illicit drug use.

The medical history section will capture information about exposures that could lead to HIV transmission. The section on other potential risk factors 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. Information from the section on work place exposures will be asked only if a donor indicates they have no sexual, drug-related, or medical risks. However, donors who work in a health care profession or other social settings that could lead to exposure to blood or other body fluids could be at higher risk for HIV acquisition. Exposure and treatment questions will be used to ascertain if the blood donor knew of his/her HIV status at the time of blood donation, self-reported route and time of infection, and past or current anti-retroviral therapy (ART). In Brazil, ART is universally available for HIV treatment. These questions will be useful for interpreting possible drug resistance patterns in the molecular surveillance component of the study. Please see *Attachment 3.2* for a detailed justification for each question.

In awareness of the possible sensitive nature of the questions, the following steps will be taken to ensure the privacy of respondents although personal identifiable information is not collected:

- The questionnaire is administered using audio computer-administered self-interview (ACASI) program. The purpose of using a self-administered instrument is to ensure 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.
- Donors 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 Brazil**

HIV Informed Consent, Attachment 2.

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

The annualized cost to respondents is estimated at \$260 based on \$6.50 per hour. It is estimated that each respondent will spend about 5 minutes completing the consent form and about 19 minutes completing the questionnaire. 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 Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Risk Factor Informed Consent	Adult Donors	100	1	5/60	8
Risk Factor Assessment	Adult Donors	100	1	19/60	32

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Form Name	Number of Respondents	Frequency of Response	Average Time per Respondent	Hourly Wage Rate *	Respondent Cost
Risk Factor Informed Consent	100	1	5/60	\$6.50	\$54
Risk Factor Assessment	100	1	19/60	\$6.50	\$206

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

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

Because this is an extension without change of a previous project 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 \$149,162 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	233	92,380
Operational Costs for Data Collection Activities –Printing, equipment, overhead, respondent reimbursement,, non-labor				48,848
Other Contractual costs for data collection, non-labor				0
Travel costs associated with data collection and study launch				1,103
Other costs, non-labor				800
Total				149,162

A.15. Explanation for Program Changes or Adjustments

This previously approved study contained a consent form and questionnaire that imposed a 24 minutes burden hour per respondent, with 2,000 respondents’ total. This consent form and questionnaire constitutes a continuation of the original 24 minutes burden hours per respondent for the approved study protocol including a consent form and questionnaire administered to HIV-positive blood donors that will be identified through routine blood donor screening. In this continuing phase of the study, no control

donors will be included, so the total number of respondents has been lowered from 2,000 to 400 with expected enrollment of no more than 100 subjects per year for the remainder of the data collection period.

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 (2 years)	Two months from OMB approval.
Data Management and Analysis	Ongoing through December 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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