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

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TABLE OF CONTENTS

SUPPORTING STATEMENT

Introduction and Summary

This Study is a reinstatement of OMB Number: 0925-0597 expiration date, February 29, 2012. 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 samples 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 by the end of February 2012, includes both a prospective surveillance and a case-control study designed to enroll all eligible HIV seropositives detected at four participating blood centers in Brazil, and to compare their epidemiological risk profiles with a group of randomly selected seronegative (control) donors. The OMB-approved protocol has three aims. **Aim A.** Perform laboratory studies (LS-EIA testing and sequencing of the pol region of the HIV genome) on linked specimens from all enrolled HIV cases, which allows for estimation of HIV prevalence and incidence relative to genotype and putative route of infection. **Aim B.** Conduct a case control study to yield self-reported data on HIV risk behaviors among prospective donors that will be used 1) as covariates in the molecular surveillance analyses described above; and 2) to suggest modifications to the current operational donor screening questionnaire. **Aim C.** Provide data on molecular genotype and drug resistance genotype, along with counseling, of all enrolled HIV positive donors to facilitate their clinical care via referral to the Brazilian national HIV treatment system.

For the next phase, the study team proposes to continue the prospective surveillance component of the currently OMB-approved protocol to enroll all eligible HIV-positive donors that 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. That is, the study in the next phase will continue with the same methodology except that only HIV-positive donors who will be identified through routine donor screening will be studied. Enrollment of HIV seronegative donors will be discontinued. The aim of the next phase will be to determine risk factors associated with HIV infection, HIV subtype, and drug resistance profile among HIV positive donors according to HIV infection status (NAT yield donors vs recent seroconverting donors vs. long-standing seropositive donors), year of donation and site of collection. The findings 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 will also examine secular trends in risk behaviors by comparing the data

previously collected to the data we plan to collect over a nearly five year period.

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 the reinstatement of 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 be directly built upon the capacities established at all 4 blood centers during participation in the previous phase of the study.

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. In 2006, the REDS-II program initiated an international component, extending the scope of blood safety research to include investigators in Brazil and China. The goal of the REDS-II International Component is to conduct epidemiologic, laboratory, and survey research on blood donors in selected resource-limited countries in regions seriously affected by the AIDS epidemic to help increase the safety and availability of blood for transfusion. The current REDS-III program seeks to further expand the research into health outcomes of blood transfusion recipients in addition to the above-stated scope under REDS-II. Furthermore, South Africa has been added to the International Component under the current program. 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.

Previously, a case control study of HIV seropositive donors and a comparison population of uninfected donors as part of the NHLBI-funded Retrovirus Epidemiology Donor Study (REDS-II) International Brazil was conducted. The new study will build off the previous study to continue risk behavior and molecular surveillance at the same four blood centers in Brazil without control donors. Data collected in this continuation of the study will be of practical use to the blood banking community. In addition to the traditional route of 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 Association. We anticipate similar requests for data generated from this study.

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 questionnaire is the same as the one that

has been used in the current, first phase of the study except that it will be used only for HIV-positive donors who will be identified through routine donor screening and there will not be a control donor group in the next phase of the study. The only modifications are a change in name to reflect the new phase of REDS (REDS-III) and the removal of one data element that defines the research participant as either a case or control. 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 confidentially) 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 confidentiality 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. 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).[1]

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.[2,3] and Europe.[4,5] A recent REDS-II publication in *Transfusion*[6] 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.[3,7] The continuation of this study at 4 blood centers in Brazil during the 5-year period of the REDS-III program will enhance the validity and interpretation of the trends in HIV prevalence and incidence observed during the 2 years of the current, 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; and we also intend to evaluate whether the Brazilian MSM policy has increased or decreased the HIV prevalence among blood donors, as no data on HIV prevalence in blood donors have been published since this new policy was implemented.

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 in Volume 70 page, 2072 on January 13, 2012. 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-II subcommittee, the REDS-II Steering Committee, and the Observational Study Monitoring Board (OSMB), and OMB. The OSMB reviewed the final protocol and provided input and comments. Revisions were made to the Informed Consent document incorporating the suggestions of the OSMB to clearly state that strict confidentiality will be maintained throughout the study. 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 Oversight 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 project will pay R$15.00 (~$USD 8.00) to reimburse participants for transportation expenses to and from the study center. This current incentive is R$3.00 more than the incentive that was paid to the study's previous participants, and is reflective of an adjustment for inflation since the study's inception in 2008.

A.10. Assurance of Confidentiality Provided to Respondents

All respondents will be assured of the actions taken to safeguard their confidentiality and will be informed about the Certification of Confidentiality granted to the REDS-III Study to protect their data from involuntary disclosure (Attachment 5). Additional efforts will be made to secure the confidentiality 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. Donors will be assured of the confidentiality of their responses. 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.

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 addition, along with the Certificate of Confidentiality, in awareness of the possible sensitive nature of the questions, the following steps will be taken to ensure the confidentiality 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 confidentiality of the information collected. See Informed Consent Document, 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 24 minutes (0.40 burden hours) including administration of the informed consent form and questionnaire completion instructions. 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

Estimated Annual Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
100	1	0.40	40

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Number of Survey Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost – all respondents
100	1	0.4	6.50	$260

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

Because this is a reinstatement 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.

A.14 - 1 Annualized Costs	
Activity	**Total Cost**
Study Recruitment Activities	7,814
Participant Enrollment and Data Collection	48,848
Data Management and Analysis	$92,500

A.15. Explanation for Program Changes or Adjustments

The previously approved study contained a 24 minute long questionnaire that

imposed a 0.40 burden hour per respondent, with 2,000 respondents total. This questionnaire constitutes a reinstatement of the identical 0.40 respondent burden hours per respondent for the approved study protocol including a 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 100 subjects per year for a four year 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 (4 years)*	Two months from OMB approval.
Data Management and Analysis	Ongoing through December 2017

* The Study Team will request an extension to collect data in the 4th year.

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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