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REDS-III International Component Brazil

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

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1. Concept Synopsis and Study Schema

The safety of the blood supply is 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 newly acquired infections may not be detected. When donors test positive for infections a series of follow-up activities are important, including informing the donor of the results. Unfortunately, donor notification of testing results is challenging and often does not occur in Brazil. Approximately 40% of donors with repeat reactive donation screening results do not return to the blood center for additional testing, notification and counseling.

On the other hand, despite the existence of free HIV counseling and testing (HCTs) sites in Brazil, blood centers remain major providers of HIV testing. The HIV case control study conducted as part of the REDS-II International Component revealed that high-risk donors are donating blood in Brazil.(1) Moreover, even with the adoption of "state of art" technology through implementation of minipool nucleic acid testing for HIV and HCV a small risk of HIV transmission remains especially for persons with very low-level viremia.(2) As part of standard procedures in Brazil, blood banks refer HIV-positive donors to HCT treatment centers with the intent of linking the donor to medical care and seeking to limit the spread of HIV through counseling on risk reduction.

Although this general understanding of donor notification and subsequent follow-up activities exists, no formal studies of the notification process and consequences on former donor behavior have been conducted in Brazil. In this protocol we will conduct a study with three aims to elucidate a deeper understanding of these topics. The first aim of the project will analyze the proportion of donors who are successfully notified of infection results from blood donation testing. In this aim we will expand the focus to include all infections that blood centers in Brazil test donations for because differences in rates of notification by 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 an audio computer-assisted structured interview (ACASI). The sample for this part of the project will be former donors who have already participated in REDS-II and REDS-III HIV-positive donor case interviews during the interval of 2008 – 2013. The goals are to understand what, if any, behavior changes were adopted to reduce further transmission of HIV and to obtain information on HIV disease progression and medical care. Finally, the third aim will consist of asking HIV-positive blood donors about ways to improve the disclosure of HIV risks during donor eligibility assessment and better understand the motivating factors that drive higher risk persons to donate blood.

To our knowledge studies assessing the effectiveness of HIV counseling and donor notification and their association with risk behavior changes are novel in Brazil and elsewhere. Results of this study may improve blood safety based on the ability to directly refer persons primarily interested in HIV testing results to HCTs before rather than after blood donation. Because our study will build off of the routine blood donor procedures of four large blood banks in Brazil, it may lead to direct changes in donor screening, notification and counseling policies in Latin America, and suggest potential modifications in countries where HIV has similar epidemiologic transmission patterns, including the US. 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 the impact on US donors who test positive for HIV and other infections.

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3. Protocol

4.1. Background and Significance:

While the prevention of transfusion-associated transmission is one of the greatest success stories in the fight against the HIV epidemic, the job is unfinished. In some middle-and low-income countries, transfusions may account for up to 6% of HIV infections.(3) At the same time, persons may be donating blood because they want to know their HIV serostatus, and these individuals are not well served by current blood bank procedures. The Brazilian standard procedures for HIV-positive blood donors is to refer these individuals to a counseling, testing and treatment center for further exams, psychological support, general orientation about risk reduction, and treatment if necessary.

Surprisingly, little is known about the consequences for donors themselves of identifying HIV infection through blood donation, or the potential public health implications of HIV infected donor notification and counseling on efforts to control the HIV epidemic. In non-donor settings, HIV counseling and testing (HCT) is the entrée to care for infected persons and when successful provides direct and indirect prevention benefits. However, before a blood donor can be linked to HCT, the 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 (4) do return for notification and counseling, but there is no published data showing how many of these 60% subsequently attend the HCT centers for follow up care and treatment. This also means that 40% do not return and may unknowingly contribute to the transmission of HIV and other infections in the broader community. Persons with HIV identified in settings outside of the blood bank are known to reduce their risk of transmitting the virus to others through viral load suppression by antiretroviral therapy (ART), behavior change following risk reduction counseling, and referrals to other preventive and social services.(5-9) However, the evidence of the impact of HIV counseling and testing on subsequent high-risk sexual behavior has been mixed. While several studies have found significant declines in the reporting of multiple partnerships and unprotected sex, other studies have found limited or negative effects of testing on behavior change.(10, 11)

Although donated blood is tested for HIV and for other infections in Brazil and other middle and low income countries, a residual risk of contamination persists due to the lag between transmissible infection (when blood contains a sufficient number of viruses) and when tests can detect the presence of the pathogen or antibodies to it (i.e., the “window period”).(12) The window period is shortened (but not eliminated) by p24 antigen or nucleic acid testing (NAT) but NAT remains unaffordable for many developing nations. NAT for HIV and HCV using a minipool format has been adopted by public blood centers in Brazil. Even so, as a means to reduce window period risk, blood banks temporarily or permanently exclude persons with risk factors for HIV from donating. Despite these efforts, HIV prevalence among donations at blood banks in Brazil and the estimated residual risk of transmission remain approximately 10-fold higher than in the US.(13-16)

During the REDS-II International Component Study, nearly 350 HIV positive donors were enrolled in four Brazilian blood centers: Fundacao Pro Sangue (Sao Paulo), Hemominas (Belo Horizonte), Hemope (Recife), and Hemorio (Rio de Janeiro) as part of an HIV risk factor case-control study.(1) For each participant an audio computer-assisted structured interview (ACASI) was conducted 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 centers. As part of an ongoing investigation of the HIV

epidemic in Brazil, we are enrolling HIV-positive donors in a REDS-III risk factor and molecular case surveillance study, from 2011-2016, resulting in an additional 500-600 (~100 per year) accruals of HIV positive donors. From this REDS-III study we will seek to enroll participants from the years 2011-2013 in the HIV counseling portion of this protocol.

In this project we will formally measure donor notification rates in Brazil and we will seek to enroll a cohort of HIV-positive donors in a follow-up study to assess linkage to health care and risk behaviors following notification of donation testing results. Our findings should yield insights into improved methods for donor selection and qualification that can increase rates of self- and on-site deferral and therefore decrease the frequency that higher-risk persons are accepted as donors in Brazil. Results of the study also have significance beyond the immediate benefit of improving blood safety at the REDS-III Brazil blood centers. The greatest potential impact will be for other developing countries, particularly in Latin American, with similar HIV disease epidemiology but few options for counseling and treatment centers, and limited resources for donation screening by NAT. In addition, since our findings on improved methods for donor notification and linkage to health care services might be generalizable to any setting where stigma and prejudice against HIV/AIDS are relevant, including settings in the US.

4.2. Objectives:

4.2.1 Primary:

Aim 1: To conduct an analysis of the proportion of donors who are successfully notified for the infections for which donations are tested in Brazil.

> **Hypothesis:** A higher proportion of donors who have markers of infections that are considered less stigmatizing, (*Trypanosoma cruzi* and HTLV) will return for notification compared to donors with markers of Hepatitis B, Hepatitis C, Syphilis and HIV.

Aim 2: To assess whether HIV-positive donors who returned to the blood center for notification and counseling subsequently attend HIV referral centers for additional counseling, treatment and follow-up, and to determine self-reported behavioral change among HIV-positive donors using ACASI.

> **Hypothesis:** Attendance to referral centers and/or primary physicians for counseling and treatment will be positively correlated with higher levels of risk behavior reduction.

Aim 3: To use HIV positive blood donors (from Aim 2) as key informants by inquiring through ACASI about ways we can improve the disclosure of HIV risks in donors during eligibility assessment.

> There are no formal hypotheses for this aim. Qualitative and quantitative analyses of the responses will be conducted to identify common themes reported by the participants.

4.2.2 Secondary Objectives for Aim 2

Two secondary outcomes will be assessed.

1. We will assess whether successful linkage of HIV-positive donors to treatment and follow up are directly related to donor access to public or private health care services on the one hand, and perceived levels of social stigma on the other.
2. We will determine if biological measures of disease progression (viral load, CD4, CD8) are associated with risk reduction.

HIV viral load and CD4/CD8 count are important indicators of infection progression and could confound the results with respect to how frequently someone attends HIV treatment clinics. Therefore, we believe collecting this information is important as it may be related to whether and how frequently donors access health care services.

4.3. Study Population or Specimens for Analyses

The study population for Aim 1 will be all donors with repeat reactive or inconclusive donation testing results who were sent request for follow-up letters from the four REDS-III Brazil blood centers in the years 2011-2013. The study population for Aims 2 and 3 will be HIV-positive donors who have previously returned to one of the REDS-III Brazil blood centers during REDS-II or REDS-III during the study years of 2008 – 2013 and who completed the HIV risk factor ACASI at one of the four REDS-III Brazil blood centers.

The 4 REDS-III Brazil blood centers maintain files which will permit data linkage to the REDS-II and REDS-III HIV participants because each center tracks the number of HIV positive donors, blood bank registration ID number (donor ID), study ID number from the REDS projects, lab sample ID numbers, date of birth, address and contact phone number. Based on this information, we will be able to identify HIV-positive blood donors, the subset who previously returned, and the subset of returning donors who completed the HIV risk factor questionnaire during REDS-II or REDS-III.

4.3.1 Inclusion Criteria:

Aim 1: *Study Subjects:* Portuguese-speaking persons aged 18–69 years who were sent notification letters consequent to infectious marker repeat reactive or inconclusive results for HIV, HCV, HBV, HTLV, syphilis or *T. cruzi* from a blood donation in 2011-2013 and who did and did not respond or return to the blood centers following receipt of the letter. The blood center notification letters are sent by standard mail with delivery confirmation. Letters that cannot be delivered are returned to the blood centers. Only donors for which delivery confirmation to the last known address the donor provided at the time of donation will be included in the study.

Aims 2 and 3: *Study Subjects:* HIV-positive Portuguese-speaking persons aged 18–69 years who participated in the REDS-II HIV case-control study or the first three years of the ongoing REDS-III HIV-positive case evaluation study (2011-2013) by completing the risk factor questionnaire and providing blood samples for molecular surveillance of HIV infection based on a blood donation given up to the end of 2013.

4.3.2 Exclusion Criteria:

Aim 1:

- Portuguese illiterate,
- Age <18 and >69 years old blood donors with negative serologic results regardless of age or literary status, and
- Donors for which the request for follow-up letter was undelivered (returned unopened to the blood center).

Aims 2 and 3:

- Portuguese illiterate,
- Age <18 and >69 years old, and
- HIV-positive donors who did not complete the risk factor questionnaire and provide blood samples during the time interval of 2008 – 2013.

4.4. Study Enrollment or Specimen Procurement

Aim 1: No subject enrollment – analysis of existing data.

Aims 2 and 3: HIV-positive donors who participated in the REDS-II HIV case-control study, or from the first three years of the ongoing REDS-III HIV-positive case evaluation study (2011-2013) will be invited to return to the blood center to participate in this further study. Based on a list of HIV-positive participants from the previous studies, a phone call will be made to invite them to participate in this new study. If the person agrees to be enrolled, a follow up letter establishing a day and time for the appointment will be sent. We plan up to two

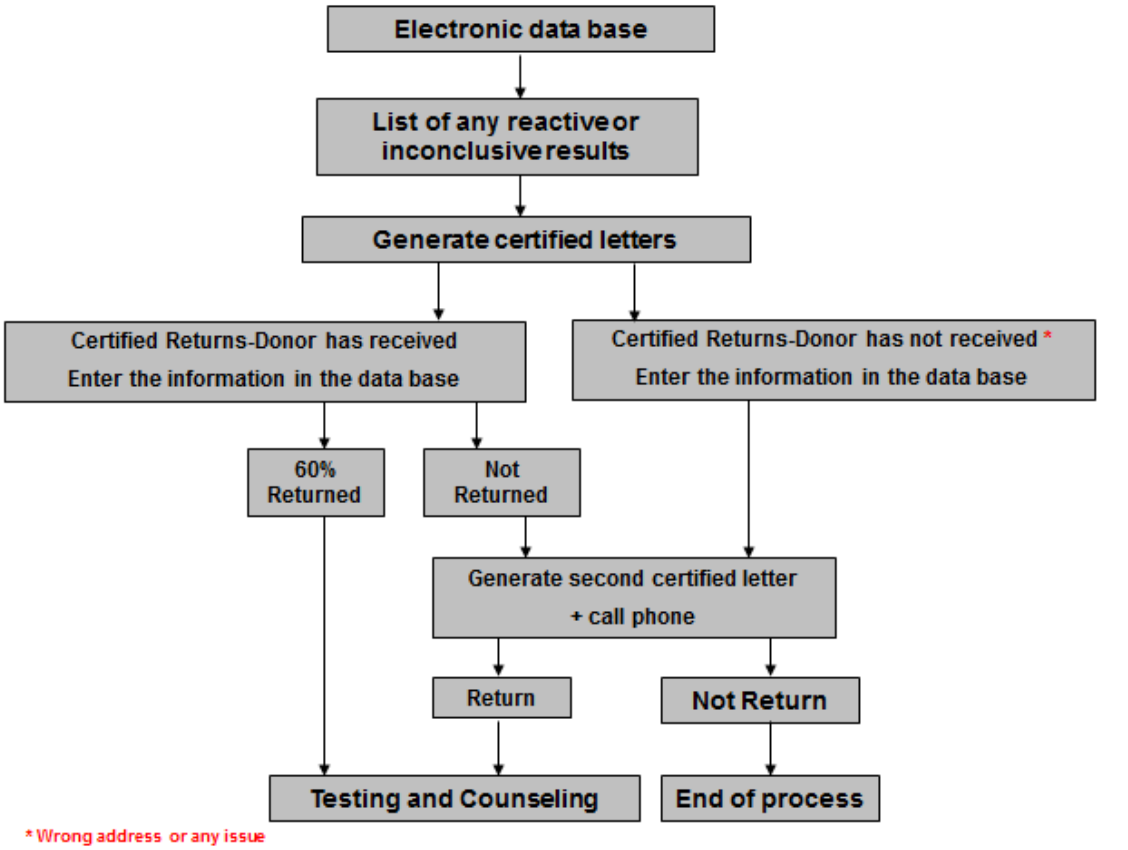
phone call attempts followed by two letter attempts to enroll each participant. A $US 35 (75 Reais) participation reimbursement will be provided to each person who completes the audio computer-assisted structured interview (ACASI) follow-up interview.

4.4.1 Screening/Recruitment/Specimen Acquisition

Aim 1: Planned study procedures are:

At the beginning of the protocol activities, the population of people meeting the Aim 1 study inclusion criteria will be generated by information systems (IS) personnel at each blood center. Common data extraction programming definitions will be established in advance to ensure comparable information is obtained from each blood center. A dataset for each site containing information on each study participant will include which markers the donor was repeat reactive or inconclusive for, information on calls and letters sent by the blood center in an attempt to contact the donor, whether and when the donor returned to the blood center for notification. These data will be transferred to RTI by secure methods so that they may be merged with Brazil donor and donation information in order to create a dataset with notification status data and donor demographics. Data from different datasets from the same blood center will be merged together using blood bank registration ID number (donor ID) and donation date. Figure 1 shows the diagram of notification tracking at one of the REDS-III centers (FPS in Sao Paulo). We will leverage similar, though not identical, databases at the three other blood centers in Brazil.

Figure 1 Diagram of Notification Tracking at FPS used to guide standard notification and operational procedures.


Electronic data base
List of any reactive or inconclusive results
Generate certified letters
Certified Returns-Donor has received
Enter the information in the data base
Certified Returns-Donor has not received *
Enter the information in the data base
60% Returned
Not Returned
Generate second certified letter
+ call phone
Return
Not Return
Testing and Counseling
End of process
* Wrong address or any issue
ttgon1/10/2013

Aims 2 & 3: Planned procedures are:

1. We will re-contact persons who participated as confirmed HIV-positive cases in REDS-II or REDS-III HIV molecular risk factor surveillance studies. The contact will be by letter or telephone and will allow us to discuss the objectives of the new study.

2. Participants who are willing to return to the blood center will have the study described in greater detail and those who consent will complete the ACASI questionnaire.

Approach: Two different approaches will be used to enroll participants.

a. **REDS-II HIV case-control study participants.** Based on a special file described in the section 4.2, a follow-up telephone call will be made by a trained physician at each blood center, asking if the person would be willing to participate in a new HIV study. A time period as long as 6 years may have elapsed since these donors participated in the HIV case-control study and so contact by telephone is the most appropriate route. The physician will explain the aims of the study and ask if the person would like to schedule an appointment. If the response is affirmative, the physician will schedule an appointment at the blood center. If more information is requested an invitation letter will be sent with the indication that we will contact the person shortly thereafter to assess interest in participating in the study.

b. **REDS-III HIV case participant**s. Participants in the HIV case surveillance study will have completed study procedures up to 3 years before the HIV counseling and notification study begins. An invitation letter will be sent to each indicating that we will contact the person shortly thereafter to assess interest in participating in the new study.

Study Procedures

1. Written informed consent for participation in the study will be obtained when the participant returns to the blood center. **Obtaining Informed Consent:** Blood centers must have signed IRB-approved Informed Consent Forms on file for every donor participating in the study. The Research Assistant will review the consent form and give the participant sufficient time to ask questions. If the subject agrees to participate, s/he will sign both copies of the informed consent form, print his/her name on the form and date the form correctly. A copy of the Informed Consent will be stored in locked filing cabinets at the each blood center until the end of the study and thereafter in accord with Brazil human subjects regulations. The other copy of the Informed Consent shall be delivered to the participant.

2. ACASI on the topics of access to health care and risk behaviors will be completed. These interviews will be completed using the netbooks that were previously purchased for the REDS-III Brazil Dengue study. Private locations in each blood center will be made available for the participant to complete the ACASI. The computers that are currently being used for the REDS-III HIV case surveillance study will not be used for this ACASI in order to avoid the possibility of the research assistant initiating the incorrect interview. Additionally, to support our objectives we will access the responses from the two previous ACASI questionnaires, namely the original HIV-positive case interviews from the REDS-II or REDS-III HIV molecular and risk factor surveillance studies.

3. Trained counselors will be on site during and after the ACASI interviews should participants want additional counseling.

4. The new ACASI survey data will be transmitted to Hemominas using the same procedures in use for REDS-III HIV case surveillance study and then transmitted to RTI.

5. We will also seek consent from each participant to obtain HIV infection status information captured in the State and National databases on HIV progression such as viral load and CD4/CD8 counts.

The Brazilian National HIV treatment and progression databases were created in 2002 by the Ministry of Health because of the need to register and monitor the care provided by VCT/medical staff, obtain demographic, behavioral and biological information regarding the individuals that attend this service. Each Brazilian VCT provides information on the individuals with HIV/AIDS (based on viral load, CD4 and CD8 information) to a data coordinating center located in Brasília. Some VCTs also provide testing for syphilis and hepatitis B and C. This information is essential for health services planning and strategies with a focus on the individual and affected communities to provide indicators of success and to support efforts to manage HIV in Brazil. In addition, this information is also being used to improve research by providing ways to access summary data for research projects. More than 500 thousand records of individuals with HIV, syphilis and hepatitis B and C are stored in this dataset. There is no time limit on how long this information is housed in databases.

4.5. Measurement

4.5.1 Schedule of Measurement

Aim 1: No participant contact is planned. The analysis will rely on existing information captured in operational databases at each blood center. However, this information must be extracted and there is currently no common method across the sites for obtaining these data. Data extraction programs will be created to identify at the individual level (each blood donor with initial positive or inconclusive serologic marker results) the following parameters: donation date, date when the letter was delivered, type of serologic marker associated with letter, if the letter was returned unopened to the blood bank, reason the letter was returned to the blood bank, number of delivered letters, date each letter was delivered, date when the donor returned for the additional sample collection, results of confirmatory testing and final date of notification/counseling following confirmatory testing. As some donors may have initial positive or inconclusive results for more than one serologic marker, and because centers may use slightly different letters for different infection marker results, we will identify which letters were sent.

Follow-up Timeline. For each blood donor with initial positive or inconclusive test result, we will allow a 12 month return for follow-up, meaning for example for those donors who received the blood bank letter in December of 2011 we will assess if they returned to the blood center up to December 2012. This procedure will allow us to determine the mean and median return time for each of the serologic markers and will give sufficient lapsed time to include all of the study participants. Depending on when the study starts, returns that may occur after a one year or longer time period will be right-censored in our analyses.

Aim 2 & 3: A single return visit to the blood center will occur for the purpose of completing a new ACASI. These return visits are planned to occur in 2015.

4.5.2 Assessment and Measurement Procedures

Aim 1: Data Sources. Data will be combined from two sources – 1) The data obtained from operational records at each site and 2) from the REDS-III Brazil donor and donation database. Demographic and testing results for the original donation that prompted notification efforts will be obtained from the REDS-III donor and donation database and merged with the information extracted from each blood centers' notification tracking databases. This *Donor notification database* will be constructed for this study and will include the blood center, donation date, donor id, infectious disease marker testing results from the index donation for donors with repeat reactive and inconclusive results for each infection marker, dates of attempted notification, indication of blood center letter delivery confirmation, date of donor return to the blood center for notification (if this occurred). See Appendix 5 for core elements of the notification database to be developed.

Aim 2 and 3: Data Sources. Data will be combined from 3 sources:

1) Data from the completed follow-up ACASI interviews conducted in this project;

Participants will complete a self-administered survey (approximately 30 minutes in length) in ACASI format which includes 10 Content Sections: Study Administrative Data, Demographic Data, Previous Donation and HIV Testing, Sexual History, Sexual Behavior and Sexual Partner Risk, Demographic and Behavioral Data on Recent Sexual Partners (Social Matrix), Medical History, General Behaviors or Exposures, Counseling and Notification and, Impact of Test-Results.

Participants who have agreed to participate in the study will be taken to a private area, for the following procedures: signing the informed consent, ~~blood collection~~ and ACASI interview.

The designated research assistant at each blood center will have an individual-level username and password for managing the ACASI computers. At the beginning of the ACASI interview the research assistant will review with the participant how to use the features of the software, after that the study participant will be left alone. At the end of the ACASI interview the research assistant will close the interview in the presence of the participant and acknowledge his/her participation. The research assistant will also facilitate referral to medical care in case the participant so requests.

The following open-ended questions in the Section: Impact of Test-Results in order to specifically inform our Aim 3 objective;

"To help us to make blood safer, what would you recommend for improving the donor selection process? Any thoughts or ideas you have are good, please say as much or little as you would like to" and,

"What could we do to get blood donors to disclose risk behaviors (we will provide explanation). Any thoughts or ideas you have are good, please say as much or little as you would like to**"**

2) Participants' answers regarding risk behaviors from the original HIV risk factor ACASI interview (REDS-II and REDS-III), allowing us to determine if risk behavior change occurred following notification, as assessed by risk behaviors reported by the donor in the period before and after HIV notification, counseling and treatment;

3) National HIV treatment and progression databases (Sistema de Informacao–Centro de Testagem e Aconselhamento in Brasilia [Brasilia SI-CTA]. This information will be obtained by investigators in Brazil and included as part of data that is transferred in the study management system to RTI. A special file with the necessary personal identifiers (blood donor's full name, date of birth, city of birth, age, mother's full name, and REDS-II or REDS-III participant ID) will be created to merge Brasilia SI-CTA laboratory data for each HIV-positive blood donor who has attended HIV counseling and treatment centers with the answers to their ACASI interviews. Following consent, these data will be obtained from the central HIV treatment records contained in Brasilia SI-CTA.(17) The data file will be transmitted through secure means to personnel at SI-CTA. The linking to treatment information will be obtained.

To be registered in the Brazilian National HIV treatment and progression database (SI-CTA) the HIV+ individual is required to provide the following data: full name, date of birth, city of birth, age, and mother's full name. Based on these variables the first search will be performed. In addition, for those individuals who may have similar/common names, birth dates or any other similarity in the required identifying information, we will use a second layer of search by merging the individual General Registration (R.G.), Cadastro de Pessoas Físicas (CPF) for "Natural Persons Register" which is a number attributed by the Brazilian revenue agency and a Unified Health System number (SUS number). These numbers can be used to search SI-CTA databases to triangulate or resolve possible matches.

Exact rules for establishing whether a match is sufficient (perfect match or probability match) for data linkage have not been developed, but will be defined before submitting to donor information to SI-CTA. We are confident that we will be able to successfully link at least 90% of this study's participants to the records housed in Brasilia. The national database was developed by one of the REDS-III co-investigators (Joao Eduardo Ferreira), thus providing ready access not only to an understanding of the content of the database, but also detailed knowledge of its development and the best approach for creating data linkages with outside information.

The database in Brasilia captures information on laboratory measures that are transmitted directly to Brasilia from health clinics and health care providers. An indication of being treated with antiretroviral therapy is captured in the Brazil database, but clinical care information such as the specific antiretroviral therapy that was prescribed is not captured electronically. We will include questions on our ACASI questionnaire to collect self-reported treatment information directly from the participants who participate in Aims 2 & 3.

To avoid ethical issues a project data manager will work in the development of this linked data set, and other study staff will have very limited access to the linking database with personal identifiers. Once linked by SI-CTA, the data will be de-identified and the unique identifier in the analysis dataset will be the REDS study ID number. A dataset containing available treatment and monitoring (CD4 and CD8) data and REDS-II or REDS-III participant ID will be returned to Sao Paulo and then forwarded to RTI for inclusion in the study analysis datasets.

Aims 2 and 3 Identifiers Linking Map (REDS databases)

Type of Identifier	Current Status	Available to Hemocenter	Available to REDS-III Brazil In country Study Personnel	Available to RTI	Available to BSRI
Personal identifiers (name, contact information, etc)	Available	Yes	Yes	No	No
Blood Bank ID (Donor ID)	Available	Yes	Yes	Yes	No
Donation Identification Number	Available	Yes	Yes	Yes	No
REDS-II HIV case control – Participant ID	Available	No	Yes	Yes	No
REDS-III case surveillance – Participant ID	Available	No	Yes	Yes	No
REDS-III Notification and HIV follow-up – Participant ID	To be defined	No	Yes	Yes	No

4.6 Specimen collection procedures

No specimens will be collected in any aim of this study.

4.7. Survey Considerations and OMB Requirements

The ACASI we plan to use for Aims 2 and 3 will require OMB clearance which will be sought in 2014.

4.8. Data Management

Five databases/data sources will be used for this study.

Aim 1: *Donor notification database* will be constructed for this study and will include the blood center, donation date, donor id, infectious disease marker testing results from the index donation for donors with repeat reactive and inconclusive results for each infection marker, dates of attempted notification, indication of blood center letter delivery confirmation, date of donor return to the blood center for notification (if this occurred).

At RTI the existing *REDS-III Brazil donor and donation database* will be accessed and data on demographic characteristics of donors and results of confirmation testing will be extracted and merged with the *Donor notification database*.

Aims 2 & 3: The study management system, the data acquisition and the transmission procedures for this study will rely on the existing approaches that are being used for the REDS-III HIV case surveillance study.

For this part of the project the following information sources will be used for analysis: *Study management system (SMS) database*, current and former ACASI *questionnaire response database from REDS-II and REDS-III , molecular surveillance dataset,* in addition to the Brazilian National HIV treatment and progression databases.

RTI will have to link the responses from the new ACASI with the existing responses from the previous HIV-positive risk factor interviews for each participant. This will be accomplished using the existing unique donor identification number and study participant number from REDS-II and REDS-III.

4.9. Data Analysis and Statistical Considerations

4.9.2 Sample Size

Aim 1: The overall percentage of discarded blood units for serologic markers varies from 4% in Sao Paulo to 8% in Recife, and in Brazil the great majority of discarded units are attributable to repeat reactive and inconclusive donation testing results**.**

Table 1. Number of delivered notification letters and blood donors returns by blood center* and infectious marker. **

Infectious Marker	Fundacao Pro-Sangue		Hemominas		Hemope		Hemorio	
	Delivered Letters n	Returning donors n (%)	Delivered Letters n	Returning Donors n (%)	Delivered Letters n	Returning donors n (%)	Delivered Letters n	Returning donors n (%)
Chagas	10	3 (30%)	29	22 (76%)	1	0 (%)	22	15(68%)
HBsAg	6	5 (83%)	34	28 (82%)	23	9 (39%)	6	2 (33%)
Anti-HBc	88	39 (44%)	326	239 (73%)	236	105 (44%)	52	12 (23%)
HCV	31	9 (29%)	38	27 (71%)	44	17 (38%)	19	6 (31%)
Syphilis	83	34 (41%)	225	165 (73%)	538	244 (45%)	119	21 (18%)
HTLV	2	2 (100%)	20	16 (80%)	36	16 (43%)	6	0
HIV	20	11(55%)	41	31 (76%)	78	34 (43%)	22	3 (14%)
Total	**240**	**103 (43%)**	**713**	**528 (74%)**	**956**	**425 (44%)**	**246**	**59 (24%)**

* Data related to one month period (August 2010 for Hemominas and Hemope, October 2013 for Hemorio, and August 2013 for Fundacao Pro-Sangue).

**Includes repeat reactive and inclusive results.

These preliminary data show marked differences in the number of persons who return following receipt of letters by blood center and infectious marker.

Using the data from the one month period described above we estimate that for a 3 year period (36 months) we will have the following total number of letters sent that will be included in our analysis of notification success (Table 2).

Table 2. Estimated number of request for return to the blood center letters delivered for repeat reactive or inconclusive testing results for all infections (HIV, HBV, HCV, HTLV, syphilis, and *T. cruzi*) at each blood center in 2011-2013.

Blood center	Approximately number of notification letters in a 3-year period
Fundacao Pro Sangue (Sao Paulo)	8,600
Hemominas (Belo Horizonte	25,600
Hemope (Recife)	34,400
Hemorio (Rio de Janeiro)	8,850
Total	77,450

Aim 2 and 3 *Sample Size*

We have estimated the expected enrollment for these aims based on the current enrollments rates for the HIV molecular and risk factor surveillance study in REDS-III (Table 1) combined with achieved enrollment from the REDS-II case control study. For REDS-III, approximately 40% of eligible HIV positive donors have enrolled in the risk factor and molecular case surveillance study. The period to the end of 2013 includes HIV-positive donors we contacted both retrospectively who tested positive before the REDS-III case surveillance study started and on an ongoing basis as infections were identified during 2013. One-hundred-seventy-eight (178) donors have enrolled in the REDS-III study as of May 2014. Because we will have recently had contact with these donors, for this protocol we expect to be able to enroll between 60% to 75% of these 178 participants, yielding 95 to 119 participants from the REDS-III case surveillance study. Assuming an enrollment rate of 50% for the 341 HIV positives from the REDS-II HIV case-control study, we will have a potential study population of 170 ~~201~~ participants from that study. Therefore, the expected participation in the counseling and follow-up study is 265 to 290 participants. We have rounded this number to an overall targeted enrollment of **275 participants**.

Table 3. Overall REDS-III HIV molecular and risk factor surveillance study enrollment by blood center May 6, 2014.

Blood center	Total enrolled (%)	Study launch
Fundacao Pro-Sangue, Sao Paulo	53/90 (59%)	11/8/2012
Hemominas, Belo Horizonte	22/76 (29%)	12/3/2012
Hemope, Recife	48/121 (39%)	12/4/2012
Hemorio, Rio de Janeiro	55/98 (56%)	12/13/2012
Total	178/385 (46%)	

4.9.4 Analytic Approach (primary, secondary and subgroup analyses)

Aim 1: Analysis of proportions of donors who return by infection type, blood center, and donor demographic characteristics. Depending on the outcome variable, modeling the proportions may require logistic regression (dichotomous) and multinomial logistic regression. In addition, we may also compare time to return to the blood center using Kaplan-Meier curves to see if there are earlier median return times for some infections compared to others. We may then compare return proportions to establish if there are statistical differences between centers in the success in notifying donors.

Aim 2 & 3: *Analysis of Risk Behaviors and Behavior Change*

Primary Predictor Variable. Self-reported attendance to clinics or health care services for HIV infection treatment.

Outcome Variables. Evidence of behavioral risk reduction (change) based on responses to the same HIV risk behavior questions at two time points spaced at least 1 year apart.

Quantitative Analyses

The demographic characteristics of the participants in the study population will be compared to HIV-positive donors over the same time frame as captured in the REDS-II and REDS-III Brazil donor and donation databases (2008 – 2013). Changes in HIV risk factors ascertained by questionnaire, including male-to-male sex, number of lifetime male and female sexual partners, number of male and female sexual partners within the past year, use of condoms, IDU, sex with an IDU, age of sexual debut will be assessed. Secondary predictors will include demographics, socioeconomic status, and other drug and alcohol use.

A study participant who is enrolled shortly after receiving notification of being HIV-positive by the blood center but has not sought follow up care may be someone who will not seek follow up care or someone who hasn't sought such care yet. We will use time-to-event analysis techniques with seeking follow-up care as the outcome. This time will be defined as the time from notification to obtaining follow-up care. Persons who have not sought care by the time of the study would be treated as censored observations with respect to analysis of linkage of donors to healthcare. This approach will allow us to account for the differential follow-up times between REDS-II and REDS-III donors who participate in this study.

Bivariate associations of specific categorical risk factors will be assessed using contingency tables with significance tests using Chi squared or Fisher's exact tests. Any risk factors with a continuous distribution or format will be assessed using logistic regression. Variables with significant or borderline bivariate associations ($p<0.15$) with confirmed HIV infection will be entered into a multiple logistic regression, multinomial logistic regression, or Cox proportional hazards regression model to assess independent associations and potential confounding. In additions, variable selection methods, i.e., forward selection, backwards elimination, and stepwise selection, may be used to identify relevant predictor variables. Key variables that will be examined to assess changes over time will include the use of condoms and the number of sexual partners in the year before the original HIV-positive blood donation and before completion of the new ACASI for this study. In addition, the number of persons with access to public or private HIV health care services will be reported.

Based on results of the HIV case control study (REDS-II), 70% of the HIV-positive participants reported high-risk behaviors (1); of those we presume that as many as 20% will not have changed their risk behaviors, but this type of assessment has not been attempted before and so is highly speculative. Assessment of and understanding lack of risk reduction (behavior change) is important from a public health perspective because it will identify those risk behaviors where additional education efforts to prevent persons from being exposed to multiple strains of HIV is necessary. We are also interested in assessing if behavior change is the same for donors who gave at each blood center or if regional differences may be evident.

We expect that if persons have records in the Brasilia SI-CTA, indicating evidence of ongoing access to health care services, risk behaviors may be different than for those donors without any evidence of being under care for HIV infection.

Qualitative Analyses We will group the study participants into two distinct groups: high and low risk behavior for qualitative analyses. These grouping will be based primarily on number of sexual partners, use of condoms, and whether illegal drug use is reported. Common themes and recommendations for questions to ask prospective blood donor that might help better identify persons with risk behaviors who should not be allowed to donate will be assessed.

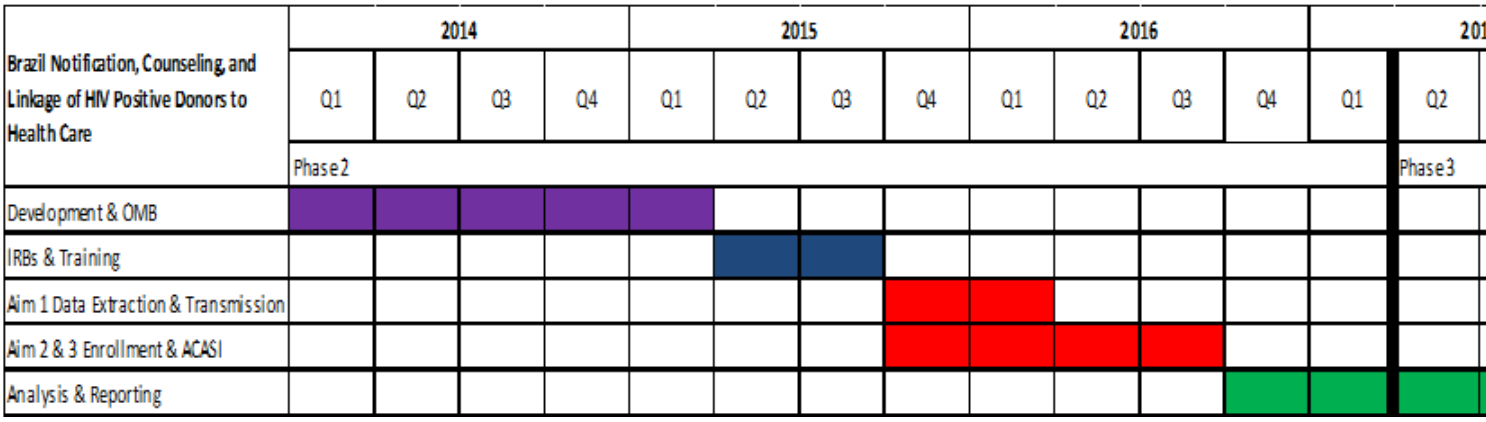
4.10. Human Subjects

This study will be approved by ethics committees and institutional review boards in Brazil and the U.S. before implementation. The main risks of this study are: 1) possible lost privacy regarding HIV or other infection status or risk behaviors; 2) possible discomfort due to the personal nature of the questionnaires. There are no direct benefits to the participants whose data we will use in Aim 1. Benefits to the participants in Aims 2 and 3 include: 1) HIV-positive donors may receive additional HIV counseling as part of the study; 2) their risk reduction may be improved by learning from the questionnaires and from the researchers. Benefits to public health in Brazil may occur by virtue of potential improvements to blood safety and control of the HIV epidemic. We will attempt to minimize risks by adhering to stringent privacy protection of the participants' data, by using trained and empathetic research personnel, ACASI interviews, and by providing counseling and medical referral for HIV infection. Informed written consent will be obtained from all participants prior to enrollment for Aims 2 and 3.

4.11. Data Security Plan (see details in Appendix 1)

For Aims 2 and 3, this study is private and not anonymous. 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. In order to conduct the linkage to the Brazil MOH (Brasilia SI-CTA) database, personal identifiers will have to be used. 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 database 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.

4.12. Study Timeline



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6. Appendices

Appendix 1 Data Security Plan

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

Brazil (In-Country) Data Security Plan

Overview:

Due to the sensitive nature of the study, the following steps will be taken to protect the personal information of individuals who are eligible, regardless of whether they participate in this study. The goal of this security plan is to put in place procedures that will reduce the risk of release of personal or sensitive information related to the eligible study population and participants. The items below are the key points to achieve the security during the study period.

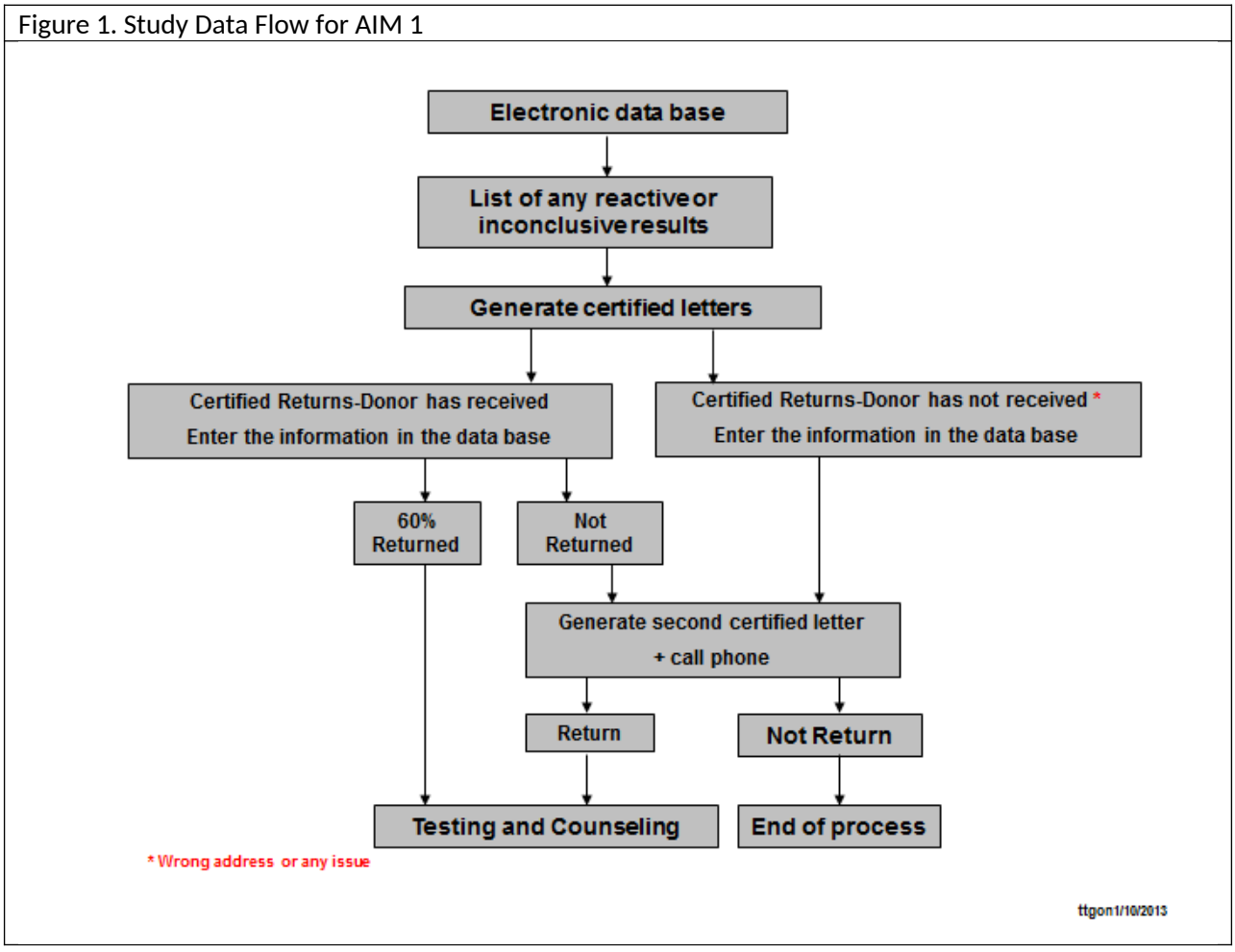
- Require the use of a two-factor authentication process to access the Study Management System (SMS)
- Store study materials in access-controlled rooms (use of key or access card to gain entry)
- Use computers with access-level control for the SMS, including:
    - Individual level username and password requirements for all staff with access to study computers
    - Separately store files with personally identifiable information (PII). These data files reside on local system that is backed up every Friday by local blood center IS or IT departments
    - Impose a mandatory screen saver after 5-minutes of inactivity
    - Study-specific usernames assigned to staff
- Instruct staff to lock computers when they leave room
- Open the study files only when they need them, and for no longer than 5 minutes
- If printing is required, print reports and other materials with identifying information on local printers in access-controlled spaces/rooms
- Staff working on the REDS-III study will sign a non-disclosure agreement as part of their training and certification on this HIV protocol.

Security Plan for Aim 1

The PI at each blood center will be responsible to designate IT personnel that will be responsible for:

The IT personnel at each blood center will generate a data file containing information on specific study participants and upload these files to RTI using the secure website file transfer procedure. The information on this file will include: 1) which markers the donor was repeat reactive or inconclusive for; 2) the number of attempts made to notify the person, the method of the attempt (calls or letters) and the corresponding dates; and 3) if and when the donor returned to the blood center for notification. Additionally, this file will include the donor ID to permit linkage with other REDS-III data sets (demographic information).

Figure 1. Study Data Flow for AIM 1



Data bank access at each Blood center

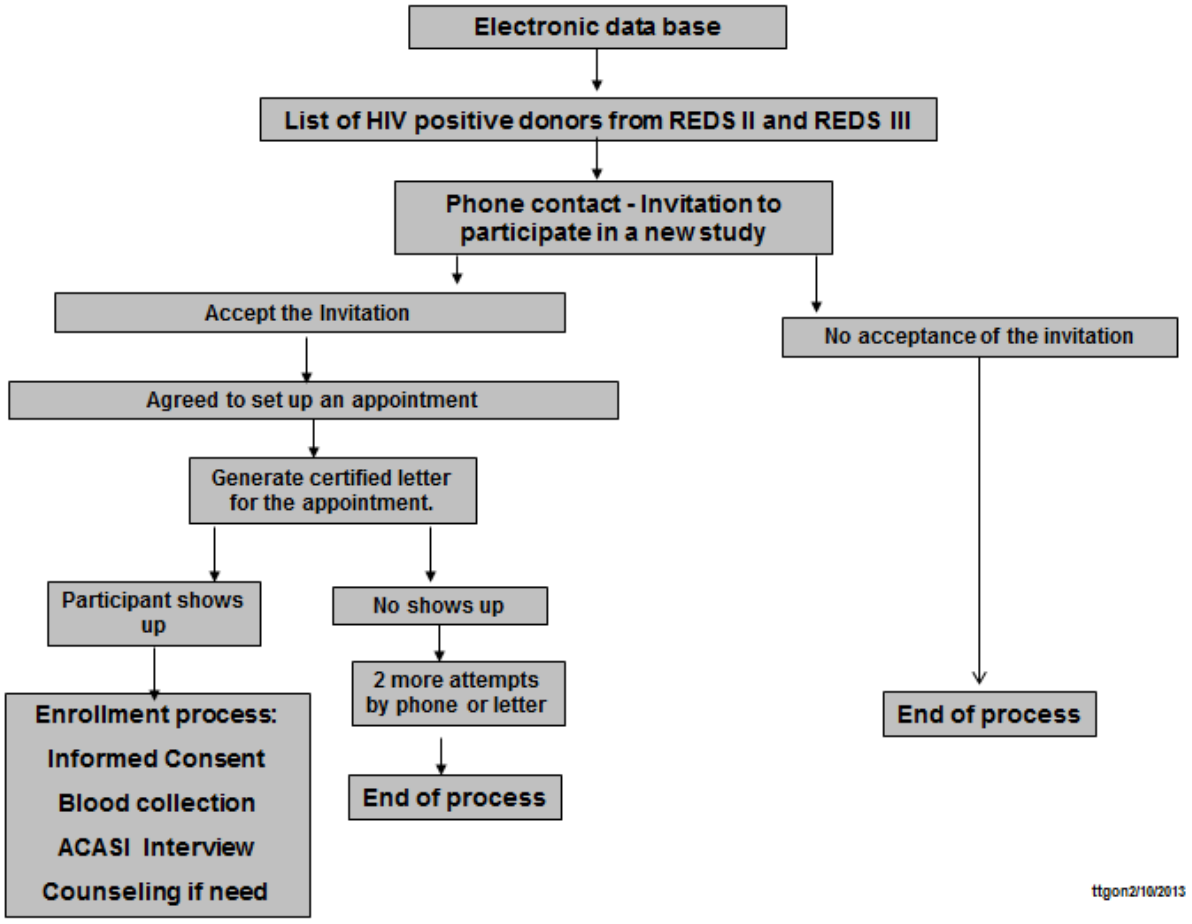
A limited number of authorized staff has approved unescorted access to the data bank. All data bank access is logged and regularly reviewed by management. Authorized access is reviewed on a monthly basis. Visitors have no access to the data bank.

Security Plan Aims 2 and 3:

Obtaining data: List of positive blood donors at each blood center

At each blood center, the current REDS-III HIV SMS will contain partial numbers of eligible donors for this protocol. For cases participating in the REDS-II Case-Control study, each blood center PI will designate one IT personnel to generate the list of the HIV positive donors and provide this information to the study coordinator. This file will contain: a) donor ID; b) full name; c) address; and, d) a current contact phone number. Using this information, the site coordinators will generate a new record in the HIV SMS for REDS-II HIV positive donors and event tracking for this protocol will occur in a singular SMS. The flow of data for AIMS 2 & 3 of this study is provided in Figure 2 (below).

Figure2. Study Data Flow for Aims 2 & 3



A designated study physician, hired specifically for this task, will then call each one of HIV positive donors inviting them to participate in the study. A follow-up letter will be sent if the persons agree to participate in the study. This letter will be prepared by this study physician. The letter postage will follow the regular blood bank procedures. For those persons who were contacted by phone but refuse to be part of the study, the SMS will indicate refusal to participate; no follow up invitation attempts will be made.

For those who agree to participate by phone, the study coordinators will send a follow up invitation letter by mail. The HIV SMS contains details on the various study activities, including attempts to enroll and complete the study with the donor. If someone agrees to participate but does not show up after two attempts to get them to attend an appointment at the blood center, the SMS is updated to reflect a status of “lost to follow up” or “no show”. Following the processes established for the REDS-III HIV Risk Factor and Molecular Surveillance protocol, invitation letters will be generated manually outside of the HIV SMS, but the site coordinators will update the SMS each time a letter is generated.

All hardcopy documents, and any study report/listings eligible or participating donors will be kept in locked drawers, and within a locked study office. Access to the list of HIV positive donors will be controlled and available only to the study physician, the study coordinator, and the IT professional who generates the list for the study.

Participant Security Plan Aims 2 and 3:

We are utilizing best practices based on our experience with a similar protocols under the REDS-II and REDS-III programs.

Participants who have showed up for the study appointment will be taken to a private area, for the following procedures: signing the informed consent, ~~blood collection~~ and ACASI interview.

ACASI Interview: The designated research assistant for the ACASI interview will have an individual-level username and password. At the beginning of the ACASI interview the research assistant will help the participant showing how to proceed and how to use the features of the software, after that the study participant will be left alone. At the end of the ACASI interview there will be a screen*: **"You have finished the questionnaire. From now on, DO NOT touch the screen. Please, talk to the research assistant, the person who assisted you at the beginning of this questionnaire. This assistant will close the screen and acknowledge you for your participating in this study".*** The research assistant will close the interview in the presence of the participant. We will also impose that the computer will be locked after 15 minutes of inactivity, in addition to instructions to the staff to lock computers when not in use.

Sending the ACASI files to Belo Horizonte (the coordinator center): At each blood center, a designated Research Assistant will be responsible for sending ACASI files to the coordinating center in Belo Horizonte each week; he/she will his/her own username and password when compiling the ACASI data files.

Sending the ACASI files from Belo Horizonte to RTI:

A designated Study Coordinator at the Hemominas blood center in Belo Horizonte, Brazil will receive the ACASI (questionnaire) files, review and clean the data for missing or irregular values, and, then up load the files to RTI using a secure, encrypted FTP site on the private site of the REDS-III website. This coordinator has a username and password to access this FTP site for uploading data only; s/he cannot download data from this site. Handling ACASI data is assigned to a single coordinator at Hemominas in Belo Horizonte.

Individual level username and password requirements for all staff with access to study computers; the computer, files and related documents will be kept in in locked drawers, and locked rooms.

Linkage to the National HIV treatment and progression databases (Sistema de Informacao–Centro de Testagem e Aconselhamento em Brasilia [Brasilia SI-CTA]).

A highly trained IT professional at each blood center will develop an encrypted dataset containing the following information: a) the participant's name; b) date of birth; c) mothers name; d) Blood bank ID, and 5) study ID.

These encrypted dataset will be sent to the National HIV treatment and progression databases [Brasilia SI-CTA], in order to obtain viral load, CD4 and CD8 information.

At the National HIV treatment and progression databases [Brasilia SI-CTA], one of their highly trained IT professionals will merge the dataset related to CD4 and CD8 count. This new linked data set will be an encrypted file on which IT professionals at Brasilia SI-CTA provide a file with one or more records per donor as appropriate. This file will contain the following variables: a) study ID, b) viral load, c) date of viral load, d) CD4 count, e) date of CD4 count, f) CD8 count, and g) date of CD8 count for each time point such data is available. Since many of the donors who successfully match with the Brasilia SI-CT will have repeated test values over time, each record returned will reflect data for the donor on a specific date.

To minimize ethical issues, a project data manager will work in the development of this linked data set, and other study staff will have very limited access to the linking database with personal identifiers.

Appendix 2 Informed Consent

Attachment 2: Informed Consent for the effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil

OMB Number: 0925-XXXX
OMB Expiration Date: XX/XX/XXX

Appendix 2 Informed Consent

PROJECT "REDS III: RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY-III-INTERNATIONAL"

INFORMED CONSENT

INFORMED CONSENT TERMS ACCORDING TO THE POLICY OF RESOLUTION CNS 196/96 FOR THE SUB-PROJECT: "The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil"

We are inviting you to participate in the sub-project: **The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil.**

This study is part of a multicenter project entitled, "Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)," under the overall direction of Dr. Ester Sabino. The purpose of the REDS-III Brazil International program is to do research on blood safety related to the HIV virus and other infections in Brazil.

Why have we asked you to be a part of this study?

We are asking you to participate because you have participated in a previous HIV research study at this blood bank. This study is a follow-up study to the one in which you previously participated.

Who is conducting this study?

This study is being conducted by Fundação Hemominas (Minas Gerais), Fundação Pró-Sangue (São Paulo), Fundação Hemope (Pernambuco) and HemoRio (Rio de Janeiro) in Brazil, in collaboration with two US research institutes; the Blood Systems Research Institute in San Francisco, California and the Research Triangle Institute in Rockville, Maryland, United

States. Principal Investigators at the Blood Systems Research Institute and Research Triangle Institute jointly developed with the Brazilian Investigators, this scientific study protocol to be implemented in four (4) Brazilian blood banks. Furthermore the Research Triangle Institute will develop the informatics software programs that will perform the quality control and analysis of data collected from the study participants. This scientific study protocol is paid for by the National Heart, Lung and Blood Institute (NHLBI), of the National Institutes of Health (NIH) in the United States and has been approved by the respective ethics committees in Brazil and in the United States.

What is the purpose of this study?

For this project we have the following objectives:

1. To evaluate changes in behavior among HIV-positive donors since learning about their HIV status and to assess whether HIV-positive donors who return to the blood center for notification of test results and counseling subsequently attend referral centers for additional counseling, treatment and follow-up care.
2. To assess ways we can improve donors' disclosure of HIV risk factors during the clinical donor screening interview at the time of blood donation and to investigate the motivating factors that influence people when they make the decision to donate.
3. To compare the responses you give on the study questionnaire to your HIV disease progression and your treatment data that are maintained by the Ministry of Health. If you have not had any treatment or do not consent to allow us to access these data, your Ministry of Health data will not be included in this part of the study.

How many people will be part of the research?

Approximately 275 persons who are between the ages of 18 and 69 years old who have previously participated in similar HIV studies at the four blood centers in Brazil will participate in this study.

What will happen to you if you participate in this study?

If you agree to participate, using a computer in a consulting room, you will answer a questionnaire about what has happened to you since being notified of your HIV infection status at the blood center. This questionnaire will have questions related to access to health care and treatment, risk reduction after the HIV notification, HIV status disclosure to sexual partners, family and friends, stigma and prejudice and, ways you think we can enhance HIV disclosure during the donor eligibility assessment. The questions will take no more than 40 minutes to answer.

For your participation in the project, we will pay $35 USD (R$ 75) to compensate you for a meal and for your transportation to the study center.

What else can I expect if I participate in this study?

The questionnaire we will ask you to complete will be administered by computer. You will be able to read the study questions and answer options on a screen, and will also hear the questions and answer choices using headphones. You will then be able to record your answers using a computer keyboard or by touching the computer screen. The interview is intended to be conducted in private. However, the study research assistant will be available to answer any questions you have or address any other concerns.

While you are at the blood center, a trained counselor physician will be on site during and after you answer the questions on the computer. This physician will be available if you would like additional counseling. All you have to do is let the research assistant know you want to talk to the counselor physician and you will be provided a private location for any conversation you wish to have.

Are there any risks to participating in this study?

-

Due to the nature of the study, some of the questions are about private and personal matters and may make you feel uncomfortable or embarrassed. Our purpose in asking you these questions is to improve the safety of donated blood. Your participation is voluntary and you may refuse to answer any questions.

There is a small chance that your personal information may not be kept private. The highest risk of loss of privacy will occur when we seek to obtain information on your treatment from the Brazil Ministry of Health because we have to send information including your name, date of birth, and your mother's maiden name to the Ministry of Health. However, we emphasize that, to ensure the privacy of information collected from each participant, the researchers have developed a thorough Data Security Plan. A highly trained IT professional at each blood center will develop an encrypted dataset for each participant containing the following information: a) the participant's name; b) date of birth; c) mother's name; d) blood bank ID, and 5) study ID. Study subjects' encrypted datasets will be sent to the National HIV Treatment and Progression Databases [Brasilia SI-CTA], in order to obtain viral load, CD4 and CD8 information.

At the Brasilia SI-CTA, one of their highly trained IT professionals will merge the blood center dataset with the Brasilia SI-CTA data related to viral load, CD4 and CD8 counts. This new linked dataset will be an encrypted file and may include one or more records per participant, as appropriate. This file will contain the following variables: a) study ID, b) viral load, c) date of viral load, d) CD4 count, e) date of CD4 count, f) CD8 count, and g) date of CD8 count.

Treatment information returned to us from the Ministry of Health will only include the study number that has been assigned to you. The questionnaire will be identified by unique numbers and not your name. The datasets used for analysis will never contain information that can personally identify you. The answers that you provide will be combined with the answers from all other participants who complete the questionnaire. Study investigators will never disclose individual responses to any question. You can be assured of privacy of the research conducted by the study team and investigators, before, during and after the study.

If you would like more detailed information about our data security plan, please inform the research assistant and you may read the complete Data Security Plan text.

Are there benefits?

There are no direct benefits to you for participating in this study. Your participation may help blood centers to understand if we are successfully linking HIV positive blood donors to treatment in Brazil, or if improvements are necessary. In addition your answers may help us to improve blood donor selection procedures in the future, potentially improving blood safety in Brazil.

If I decide to participate in this study, what are my rights?

You can choose to participate or not in this study. Regardless of your decision, there is no penalty and there will be no impact on your routine medical care. Also, if you choose to participate in the study now and leave the study later, this will not affect your medical care.

If you decide in the future that you do not want your information to be used in this study, you can notify the blood center in writing at any time. As soon as we receive your notification, we will destroy any information which was collected for this research study.

In addition, you may choose to accept or not to accept the collection of the following information:

1. We will ask you to allow us to collect information regarding your HIV viral load and CD4/CD8 counts, which are important indicators of infection progression. These data will be obtained from the central HIV treatment records contained in the Sistema de Informacao–Centro de Testagem e Aconselhamento in Brasilia (Brasilia SI-CTA) kept at the Brazilian Ministry of Health. For that we will need your mother's name, and your date of birth. This information, along with your name, will be compared to records kept by Brasilia SI-CTA. Information the Brasilia SI-CTA has on your treatment will be sent back to us under a code that will not directly identify you by name so that we can include it in our analysis dataset for this study.

HIV Viral Load and CD4/CD8 agreement:

_____ Yes, I allow the researchers to access my viral load, CD4 and CD8 results from the Brasilia SI-CTA records**.**

My mother's complete name (please print):
_____

My date of birth: _____/_____/_____

City of Birth: _____/ State:_____

My current age: _____

R.G:_____

CPF:_____

Unified Health System number: _____

_____ No, I do not allow the researchers to access my viral load, CD4 and CD8 results from the Brasilia SI-CTA records.

Who can answer my questions about the study?

Any questions you have will be answered by researchers at the blood bank before, during and after your visit to the blood bank for this research project: Dr. XXXXXX, address XXXXX, Monday to Friday, business hours XXXXXXX.

You can also speak with Dr. Ester Sabino, Principal Investigator in Brazil, by phone (011) 3061-8702 or e-mail sabinoec@gmail.com

Consent:
I DECLARE THAT I HAVE READ AND UNDERSTOOD ALL THE INFORMATION AND I AGREE TO PARTICIPATE IN THE ABOVE RESEARCH. I AM FREE TO RETRACT MY CONSENT IN ANY PHASE OF THE RESEARCH STUDY IF I DO NOT WANT TO CONTINUE PARTICIPATING, WITHOUT CAUSING ANY CHANGE TO MY RELATIONSHIP WITH THE BLOOD CENTER.

Name and signature of the study participant:

Name: _____

Signature: _____

Date: _____/_____/_____

_____
Investigator

Dra. Ester C. Sabino : (011) 3061 8702
Faculty of Medicine, University of São Paulo (USP)

Appendix 3 Follow-up ACASI survey of HIV-positive donors

HIV NOTIFICATION AND COUNSELING (English)

SECTION A - STUDY DATA

READ AND HEARD: This section is to be completed by the research assistant or other research staff

A1. **NOTIFICATION STUDY SUBJECT ID**

— — — — — — — —

A2. **REDS-II /REDS-III RF Subject Study ID:**

— — — — — — — —

A3. **Subject Type** (Choose one)

__ Case

A4. **Study participation site** (Choose one)

31 HEMOPE - Pernambuco

32 FPS - Sao Paulo

33 HEMOMINAS - Minas Gerais

34 HEMORIO-Rio de Janeiro

SECTION A – STUDY DATA

A5. **Month of interview** (Choose one)

01	January
02	February
03	March
04	April
05	May
06	June
07	July
08	August
09	September
10	October
11	November
12	December

A6. **Year of interview (please enter four numbers)**

__ __ __ __ yyyy

A7. **Research Assistant Initials: __ __ __ __ __**

***READ AND HEARD*: If study subject is not already sitting at the computer, at this time please make sure the study subject is sitting at the computer and has put the headphones on.**

SECTION B - DEMOGRAPHIC DATA

***READ AND HEARD*: This study has been approved by Ethical Committees in Brazil (CONEP approval #XXXXX) and in the USA (IRB# XXXXX).**

This study also has been approved by the Office of Management and Budget; OMB XXXXXXX, OMB approval expires XX, XXXXX, XXXX. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB clearance number.

***READ AND HEARD*: The estimated time for collecting the information contained in this questionnaire is 40 minutes, on average, including time for reviewing instructions, responding to questions, and any answer revisions.**

***READ AND HEARD*: The following questions are about your general characteristics. Please, respond as truthful as you can, and keep in mind that your answers are anonymous and will be reported together with all other participants who complete this questionnaire. We know that you have answered some of these questions before. We are asking them again because they will help us understand your current living situation.**

***READ AND HEARD*: From now on, you will be left alone. It means that you will have privacy to answer this survey. Please, if you have any questions call the research assistant for help.**

B1. **What is your gender?**

1 Male

2 Female

7 Don't Know

8 Refuse to Answer

SECTION B - DEMOGRAPHIC DATA

B2. **What is your current marital status?** (Choose one)

1 Single, never married.

2 Living together, but not legally married.

3 Married.

4 Separated/divorced.

5 Widowed.

7 Don't Know

8 Refuse to Answer

If B2 is not equal to 2 and B2 is not equal to 3, then skip to B4.

B3. **If you are married or living with someone, is your spouse/cohabitating partner** (Choose one)

0 Male

1 Female

2 Transgender

7 Don't Know

8 Refuse to Answer

B4. What level of education do you have? (Choose one)

00	Never been to school
01	Adult alphabetization
02	Did not finish elementary school
03	Elementary school
04	High school
05	Technical or professional school
06	College
07	Post-graduation/ Master/Doctoral
97	Don't Know
98	Refuse to Answer

B5. **Are you presently employed?**

1	Yes
0	No
7	Don't Know
8	Refuse to Answer

B6. **What is your occupation?**

— —

Section C - Previous donation and HIV testing

***READ AND HEARD*: The following questions are about blood donation and HIV testing. Please, respond as truthfully as you can. Your answers are anonymous and will be reported together with all other participants who complete this questionnaire.**

C1. **Since you learned of your HIV test result, have you tried to donate blood at this or another blood center?**

1 Yes

0 No ***Skip to C4***

7 Don't Know

8 Refuse to Answer

C2. **Since you learned of your HIV test result, how many times have you tried to donate blood at this or at another blood center?** (Choose one)

1 1 time

2 2 or more times

7 Don't Know

8 Refuse to Answer

C3. **What was the reason for your attempted blood donation? Please check all the boxes for the factors that contributed to your decision to come to a blood center after you learned about your previous HIV test result. When you have selected all of your answers, please touch the "Next Question" box.** (Check all that apply)

__ Only place I know of offering tests

__ Testing is free

__ Testing is confidential

__ Testing is more accurate than at other sites

__ Testing is more convenient than at other test sites

__ I wanted to double check the HIV test result

__ I wanted to know about test results other than HIV

__ Other

__ Don't Know

__ Refuse to Answer

C3b. **Please specify any other reason for donating blood.**

— —

C4. **Since you learned of your HIV test result from the blood center, have you been tested for HIV somewhere else?**

1 Yes

0 No ***Skip to C8***

7 Don't Know

8 Refuse to Answer

C5. **Since you learned of your HIV test result from the blood center, where have you been tested for HIV?** (Choose one)

1 Private lab

2 Counseling and Testing Centers (CTA's)

3 Hospital

4 Public lab

5 Blood bank

6 Other place

7 Don't Know

8 Refuse to Answer

If C5 is not equal to 6, then skip to C5c.

C5b. **Please specify the other test site.**

— —
— —

C5c. **When was the last time you were tested for HIV? Please tell us the month and year if you can remember.**

— — / — — — — mm / yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

2099 Not Applicable (Year)

SECTION C – PREVIOIUS DONATION AND HIV TESTING

C6. **Since you learned of your HIV test result from the blood center, how many times have you been tested for HIV?** (Choose one)

1 1 time

2 2 times

3 3 or more times

7 Don't Know

8 Refuse to Answer

C7. **Overall, how would you rate your HIV testing experience at locations other than the blood center?** (Choose one)

0 Very satisfactory

1 Satisfactory

2 Unsatisfactory

3 Very unsatisfactory

7 Don't Know

8 Refuse to Answer

If C7 is not equal to 2 or C7 is not equal to 3, then skip to C7c.

C7b. **Please check all the boxes for the factors that contributed to your unsatisfactory or very unsatisfactory HIV testing experience.** (Check all that apply)

__ Long wait at the testing site

__ The testing site was crowded.

__ The testing site is too close to my house.

__ The testing site is too far away from my house.

__ There is a lack of privacy at the testing site.

__ The counseling session takes too long.

__ The HIV result takes too long of time to get.

__ The HIV test result is not accurate.

__ I unexpectedly met an acquaintance and did not feel comfortable.

__ I am not confident in the quality of the equipment and facilities.

__ The staff at the testing site was not nice to me.

__ Other reason

__ Don't Know

__ Refuse to Answer

If C7bK is not equal to 0, then skip to C8.

C7c. **Please specify the other reason for your unsatisfactory or very unsatisfactory HIV testing experience**

— —

SECTION C – PREVIOIUS DONATION AND HIV TESTING

C8. **Counseling and Testing Centers (CTA) are health services that provide diagnosis and prevention services for sexually transmitted diseases. At CTA's you can obtain free and confidential testing for HIV, syphilis and hepatitis B and hepatitis C among other services. Have you ever heard about the Counseling and Testing Centers?**

1	Yes	
0	No	***Skip to instruction before D1***
7	Don't Know	
8	Refuse to Answer	

If C8 is equal to 0, then skip to instruction before D1.

C9. **Have you ever been tested at a Counseling and Testing Centers (CTA)?**

1	Yes	
0	No	***Skip to instruction before D1***
7	Don't Know	
8	Refuse to Answer	

C10. **When was the last time you were tested at a Counseling and Testing Centers (CTA)? Please specify the month and year.**

__ __ / __ __ __ __	mm / yyyy
2097	Don't Know (Year)
2098	Refuse to Answer (Year)
2099	Not Applicable (Year)

Section D - Sexual History

READ AND HEARD: Now we want to ask about the people you have had sex with or your sexual partners **since you learned of your HIV test result.** We understand that these questions are about intimate and private matters, which could make you uncomfortable. Please keep in mind that the questions are part of a scientific study. Please answer these questions to the best of your knowledge and as truthfully as you can.

D1. **As of today, what do you consider yourself to be?** (Choose one)

1 Straight/heterosexual

2 Bisexual

3 Gay/homosexual

4 Transgender

(**Transgender definition: People who were assigned a sex, usually at birth and based on their genitals, but who feel that this is a false or incomplete description of their sexual identity)**

7 Don't Know

8 Refuse to Answer

READ AND HEARD: The following questions will ask you about your sexual experiences. In these questions, include only those people you have had oral, vaginal, or anal sex with. Do not include people that you have just kissed. Please note: For the next few questions the terms "sexual contact" and "sex" refer to any of the following activities, whether or not a condom or other protection was used: **Vaginal sex** (vaginal sex is when a man inserts his penis into a woman's vagina), **Oral sex** (oral sex is when a partner puts his/her mouth on your sex organs or you put your mouth on his/her sex organs), **Anal sex** (anal sex, when a man inserts his penis into his partner's anus).

D2. (Ask of Men Only) **How many different women have you had sex with since you first began having sex?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

SECTION D – SEXUAL HISTORY

D3. (Ask of Men Only) **How old were you when you had sex with a woman for the first time?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

D4. (Ask of Men Only) **How many different men have you had sex with since you first began having sex?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

D5. (Ask of Men Only) **How old were you when you had sex with a man for the first time?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

If D3 is equal to 0 and D4 is equal to 0 and B1 is equal to 1, then skip to instruction before G1.

D2. (Ask of Women Only) **How many different men have you had sex with since you first began having sex?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

SECTION D – SEXUAL HISTORY

D3. (Ask of Women Only) **How old were you when you had sex with a man for the first time?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

D4. (Ask of Women Only) **How many different women have you had sex with since you first began having sex?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

D5. (Ask of Women Only) **How old were you when you had sex with a woman for the first time?**

— — — —

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

If D3 is equal to 0 and D4 is equal to 0 and B1 is equal to 2, then skip to instruction before G1.

Section E - Sexual Behavior and Sexual partners risks

***READ AND HEARD*: Now, we want to ask about the people you have had sex with or your sexual partners. We will also ask you about some of their risks for HIV. Please answer these questions to the best of your knowledge.**

E1. **When was the last time you have had sex or intercourse with man? (Please tell us the month and year)**

__ __ / __ __ __ __ mm / yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

2099 Not Applicable (Year)

E2. **When was the last time you have had sex or intercourse with woman? (Please tell us the month and year)**

__ __ / __ __ __ __ mm / yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

2099 Not Applicable (Year)

E3. **Since you learned of your HIV test result, how many men have you had sex with? Please include both ongoing sexual partners and one-time encounters.** (Choose one)

__ Zero ***Skip to E4***

__ 1

__ 2 to 5

__ More than 5

__ Don't Know

__ Refuse to Answer

SECTION E – SEXUAL BEHAVIORS AND SEXUAL PARTNER RISKS

If E3 is equal to 0, then skip to E5.

E4. **With regard to your ongoing sexual partners and one-time encounters with men, how often did you use condoms when you had sex?** (Choose one)

0 Never

1 Sometimes

2 Always

7 Don't Know

8 Refuse to Answer

E5. **Since you learned of your HIV test result, how many women have you had sex with? Please include both ongoing sexual partners and one-time encounters.** (Choose one)

0 Zero ***Skip to instruction before E7***

1 1

2 2 to 5

3 More than 5

7 Don't Know

8 Refuse to Answer

If E5 is equal to 0, then skip to instruction before E7.

E6. **With regard to your ongoing sexual partners and one-time encounters with women, how often did you use condoms when you had sex?** (Choose one)

0 Never

1 Sometimes

2 Always

7 Don't Know

8 Refuse to Answer

SECTION E – SEXUAL BEHAVIORS AND SEXUAL PARTNER RISKS

***READ AND HEARD*: We are now going to ask you about things that you may have happened to you. No one will know the answers you tell us. If any of these questions make you uncomfortable you may skip them. You may also tell the research assistant if you would like to talk to someone after completing the questionnaire.**

E7. **Have you ever been physically abused? (Please do not consider sexual abuse when answering this question).**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E8. **Since you learned of your HIV test result, have you been physically abused?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E9. **Have you ever been sexually abused or forced to have sex without your consent?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

SECTION E – SEXUAL BEHAVIORS AND SEXUAL PARTNER RISKS

E10. **Since you have learned of your HIV test result, have you been sexually abused or forced to have sex without your consent?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E11. **Since you learned of your HIV test result, have you had sex with anyone who was an intravenous drug user?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E12. **Since you learned of your HIV test result, have you had sex with anyone who tested positive for hepatitis?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E13. **Since you learned of your HIV test result, have you had sex with anyone who tested positive for HIV?**

1 Yes

0 No ***Skip to E15***

7 Don't Know

8 Refuse to Answer

E14. **Since you learned of your HIV test result, how many different HIV positive partners have you had?** (Choose one)

0 Zero

1 1

2 2 to 5

3 More than 5

7 Don't Know

8 Refuse to Answer

E15. **To the best of your knowledge, if any of your partners were HIV positive, were they taking HIV medications?** (Choose one)

0 Yes, all of them

1 Yes, some of them

2 No, none of them

7 Don't Know

8 Refuse to Answer

E16. (Ask of Women Only) **Since you learned of your HIV test result, have you had sex with a man who has had sex with another man?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E17. **Since you learned of your HIV test result, have you had sex with anyone who received a blood transfusion?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E18. **Since you learned of your HIV test result, have you had sex with anyone who was a hemophiliac?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

E19. **Since you learned of your HIV test result, have you had sex with anyone who has spent three or more nights in jail, prison, or a detention center?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

9 Not Applicable

E20. **Since you learned of your HIV test result, have you had sex with anyone who had a job that involved exposure to blood or other body fluids?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

SECTION E – SEXUAL BEHAVIORS AND SEXUAL PARTNER RISKS

***READ AND HEARD*: Now we are going to ask you some general questions regarding sexual behavior and history. We are asking you to respond as truthfully as you can. The answers are anonymous. Your answers will be reported together with all other people who complete the questionnaire.**

E21. **Since you learned of your HIV test result, have you exchanged (given or received) money or drugs, gifts or trips for sex?**

1 Yes

0 No ***Skip to E23***

7 Don't Know

8 Refuse to Answer

E22. **When was the last time that you have you exchanged money or drugs, gifts or trips for sex?**

__ __ / __ __ __ __ mm / yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

2099 Not Applicable (Year)

E23. **Since you learned of your HIV test result, have you smoked or snorted illegal drugs?** (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

E24. **Since you learned of your HIV test result, have you used or shot up injection drugs (examples include heroin, cocaine, and amphetamines)?** (Choose one)

0	No	***Skip to E26***
1	Yes	
7	Don't Know	
8	Refuse to Answer	

E25. **When was the <u>last year</u> you injected drugs?**

__ __ / __ __ __ __	mm / yyyy
2097	Don't Know (Year)
2098	Refuse to Answer (Year)
2099	Not Applicable (Year)

E26. **Since you learned of your HIV test result, have you injected any non-prescription substances including vitamins, anabolic steroids, or hormones?** (Choose one)

0	No	***Skip to instruction before E28***
1	Yes	
7	Don't Know	
8	Refuse to Answer	

E27. **When was the last time you injected non-prescription substances including drug, vitamins, anabolic steroids or hormones?**

__ __ / __ __ __ __	mm / yyyy
2097	Don't Know (Year)
2098	Refuse to Answer (Year)
2099	Not Applicable (Year)

If E24 is equal to 0 and E26 is equal to 0, then skip to E29.

E28. **Since you learned of your HIV test result, have you shared needles or syringes with another person?**

1	Yes	
0	No	***Skip to instruction before F1***
7	Don't Know	
8	Refuse to Answer	

E29. **When was the last time that you shared needles?**

__ __ / __ __ __ __	mm / yyyy
2097	Don't Know (Year)
2098	Refuse to Answer (Year)
2099	Not Applicable (Year)

Section F - Social Matrix

READ AND HEARD: This next set of questions is about sexual experiences you may have had **in the 12 months BEFORE today.** While some people have had a lot of sexual experience, others have not, so questions may or may not apply to you. Please answer these questions as accurately as possible. Remember that answers that you provide will be combined with those from all other people who complete the questionnaire and we will never disclose individual responses to any question. Specifically, we will ask about sexual activities that include vaginal and anal sex. Please answer these questions to the best of your knowledge and as truthfully as you can.

F1. **How many people have you had sex in the last 12 months?**

__ __

97 Don't Know

98 Refuse to Answer

If F1 is equal to 0, then skip to F2.

***READ AND HEARD*: Now we're going to ask you specific questions about your sex partners. If you had more than five partners in the 12 months BEFORE this interview, we are only going to ask you about the five most recent sex partners. Please start with the most recent sex partner or encounter that you had BEFORE this interview and then move back in time. Please be sure to focus on the sex partners you have had after your HIV result. When you answer the questions keep in mind we are asking about your partners after you received your HIV test results.**

F2. **What is Partner 1's gender?** (Check all that apply)

__ Male

__ Female

__ Transgender

__ Don't Know

__ Refuse to Answer

SECTION F – SOCIAL MATRIX

F3. **How old is partner 1?**

— —

97 Don't Know

98 Refuse to Answer

F4. **What type of partner is partner 1?** (Choose one)

1 Anonymous - Did not know, met for sex, never plan to see again

2 One time - Already knew person, but had sex only once

3 Acquaintance - Had sex more than once but not regularly

4 Friend (you socialize with this person) - Had sex more than once but not regularly

5 Main partner - Your spouse or main sex partner

6 Sex worker - Money or other goods were exchanged for sex

7 Don't Know

8 Refuse to Answer

F5. How would you describe partner 1's race or ethnicity? (Choose one)

1 Caucasian

2 Black

3 Asian

4 Mulatto/Pardo

5 Indian

7 Don't Know

8 Refuse to Answer

If E11 is equal to 0, then skip to F6.

SECTION F – SOCIAL MATRIX

If E11 is equal to 1, then skip to instruction before F7.

F6. Is partner 1 an injection drug user? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

If F2 is equal to 2, then skip to F8.

F7. Is partner 1 a male who has had sex with other males? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

F8. What is partner 1's HIV status? (Choose one)

1 Positive

2 Negative

3 Unknown

8 Refuse to Answer

F9. **Where did you first meet partner 1?** (Choose one)

01	Bar, cafe, nightclub, restaurant, gym or athletic activity
02	Sex club, bathhouse
03	Street, park, library, public transportation
04	Parties, clubs, political function or church
05	Internet
06	Dating service, newspaper ads
07	Carnival
08	Work
09	Met some other way
97	Don't Know
98	Refuse to Answer

If F9 is not equal to 9, then skip to instruction before F11.

F10. Specify where you met partner 1:

— —
— — — — — — — — — — —

If B1 is equal to 1 and F2 is equal to 0, then skip to F15.

If B1 is equal to 1 and F2 is equal to 1, then skip to F11.

If B1 is equal to 2 and F2 is equal to 0, then skip to F11.

If B1 is equal to 2 and F2 is equal to 1, then skip to instruction before F19.

SECTION F – SOCIAL MATRIX

F11. **Number of times you had vaginal intercourse with partner 1 in past 12 months.** (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F11 is equal to 0, then skip to F13.

F12. When you had vaginal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

F13. Number of times you had anal intercourse with partner 1 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F13 is equal to 0, then skip to instruction before F19.

F14. When you had anal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

Skip to instruction before F19.

F15. (Ask of Men Only) Number of times you had insertive anal intercourse (your penis inserted into your partner's anus) with partner 1 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F15 is equal to 0, then skip to F17.

F16. When you had insertive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every time

__ Don't Know

__ Refuse to Answer

SECTION F – SOCIAL MATRIX

F17. Number of times you had receptive anal intercourse (your partner's penis inserted into your anus) with partner 1 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F17 is equal to 0, then skip to instruction before F19.

F18. When you had receptive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every times

__ Don't Know

__ Refuse to Answer

If F18 is equal to 0, then skip to instruction before F19.

If F1 is equal to 1, then skip to instruction before G1.

***READ AND HEARD*: The next set of questions is about your second most recent sexual partner in the last year, after you have learned about your HIV positive result.**

SECTION F – SOCIAL MATRIX

F19. What is Partner 2's gender? (Check all that apply)

__ Male

__ Female

__ Transgender

__ Don't Know

__ Refuse to Answer

F20. How old is partner 2?

__ __

97 Don't Know

98 Refuse to Answer

F21. What type of partner is partner 2? (Choose one)

1 Anonymous - Did not know, met for sex, never plan to see again

2 One time - Already knew person, but had sex only once

3 Acquaintance - Had sex more than once but not regularly

4 Friend (you socialize with this person) - Had sex more than once but not regularly

5 Main partner - Your spouse or main sex partner

6 Sex worker - Money or other goods were exchanged for sex

7 Don't Know

8 Refuse to Answer

F22. How would you describe partner 2's race or ethnicity? (Choose one)

1 Caucasian

2 Black

3 Asian

4 Mulatto/Pardo

5 Indian

7 Don't Know

8 Refuse to Answer

If E11 is equal to 0, then skip to F23.

If E11 is equal to 1, then skip to instruction before F24.

F23. Is partner 2 an injection drug user? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

If F19 is equal to 2, then skip to F25.

F24. Is partner 2 a male who has had sex with other males? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

SECTION F – SOCIAL MATRIX

F25. What is partner 2's HIV status? (Choose one)

1 Positive

2 Negative

3 Unknown

8 Refuse to Answer

F26. Where did you first meet partner 2? (Choose one)

01 Bar, cafe, nightclub, restaurant, gym or athletic activity

02 Sex club, bathhouse

03 Street, park, library, public transportation

04 Parties, clubs, political function or church

05 Internet

06 Dating service, newspaper ads

07 Carnival

08 Work

09 Met some other way

97 Don't Know

98 Refuse to Answer

If F26 is not equal to 9, then skip to instruction before F28.

F27. Specify where you met partner 2:

_____

If B1 is equal to 1 and F19 is equal to 0, then skip to F32.

If B1 is equal to 1 and F19 is equal to 1, then skip to F28.

SECTION F – SOCIAL MATRIX

If B1 is equal to 2 and F19 is equal to 0, then skip to F28.

If B1 is equal to 2 and F19 is equal to 1, then skip to instruction before F36.

F28. Number of times you had vaginal intercourse with partner 2 in past 12 months. (Choose one)

__ none

__ 1 to 3 times.

__ 4 to 10 times.

__ more than 10 times.

__ Don't Know

__ Refuse to Answer

If F28 is equal to 0, then skip to F30.

F29. When you had vaginal sex, how frequently did you use condoms? (Choose one)

__ Never

__ Sometimes

__ Every time

__ Don't Know

__ Refuse to Answer

If F29 is equal to 0, then skip to F30.

SECTION F – SOCIAL MATRIX

F30. Number of times you had anal intercourse with partner 2 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F30 is equal to 0, then skip to instruction before F36.

F31. When you had anal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

Skip to instruction before F36.

F32. (Ask of Men Only) Number of times you had insertive anal intercourse (your penis inserted into your partners anus) with partner 2 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

SECTION F – SOCIAL MATRIX

If F32 is equal to 0, then skip to F34.

F33. When you had insertive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every time

__ Don't Know

__ Refuse to Answer

F34. Number of times you had receptive anal intercourse (your partner's penis inserted into your anus) with partner 2 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F34 is equal to 0, then skip to instruction before F36.

F35. When you had receptive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every times

__ Don't Know

__ Refuse to Answer

If F35 is equal to 0, then skip to instruction before F36.

SECTION F – SOCIAL MATRIX

If F1 is equal to 2, then skip to instruction before G1.

***READ AND HEARD*: The next set of questions is about your third most recent sexual partner in the last year, after you have learned about your HIV positive result.**

F36. What is Partner 3's gender? (Check all that apply)

__ Male

__ Female

__ Transgender

__ Don't Know

__ Refuse to Answer

F37. How old is partner 3?

__ __

97 Don't Know

98 Refuse to Answer

F38. What type of partner is partner 3? (Choose one)

1 Anonymous - Did not know, met for sex, never plan to see again

2 One time - Already knew person, but had sex only once

3 Acquaintance - Had sex more than once but not regularly

4 Friend (you socialize with this person) - Had sex more than once but not regularly

5 Main partner - Your spouse or main sex partner

6 Sex worker - Money or other goods were exchanged for sex

7 Don't Know

8 Refuse to Answer

F39. How would you describe partner 3's race or ethnicity? (Choose one)

1 Caucasian

2 Black

3 Asian

4 Mulatto/Pardo

5 Indian

7 Don't Know

8 Refuse to Answer

If E11 is equal to 0, then skip to F40.

If E11 is equal to 1, then skip to instruction before F41.

F40. Is partner 3 an injection drug user? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

If F36 is equal to 2, then skip to F42.

F41. Is partner 3 a male who has had sex with other males? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

SECTION F – SOCIAL MATRIX

F42. What is partner 3's HIV status? (Choose one)

1 Positive

2 Negative

3 Unknown

8 Refuse to Answer

F43. Where did you first meet partner 3? (Choose one)

01 Bar, cafe, nightclub, restaurant, gym or athletic activity.

02 Sex club, bathhouse

03 Street, park, library, public transportation

04 Parties, clubs, political function or church

05 Internet

06 Dating service, newspaper ads

07 Carnival

08 Work

09 Met some other way

97 Don't Know

98 Refuse to Answer

If F43 is not equal to 9, then skip to instruction before F45.

F44. Specify where you met partner 3:

_____

If B1 is equal to 1 and F36 is equal to 0, then skip to F49.

If B1 is equal to 1 and F36 is equal to 1, then skip to F45.

SECTION F – SOCIAL MATRIX

If B1 is equal to 2 and F36 is equal to 0, then skip to F45.

If B1 is equal to 2 and F36 is equal to 1, then skip to instruction before F53.

F45. Number of times you had vaginal intercourse with partner 3 in past 12 months. (Choose one)

__ none

__ 1 to 3 times.

__ 4 to 10 times.

__ more than 10 times.

__ Don't Know

__ Refuse to Answer

If F45 is equal to 0, then skip to F47.

F46. When you had vaginal sex, how frequently did you use condoms? (Choose one)

__ Never

__ Sometimes.

__ Every time.

__ Don't Know

__ Refuse to Answer

F47. Number of times you had anal intercourse with partner 3 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F47 is equal to 0, then skip to instruction before F53.

F48. When you had anal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

Skip to instruction before F53.

F49. (Ask of Men Only) Number of times you had insertive anal intercourse (your penis inserted into your partners anus) with partner 3 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

SECTION F – SOCIAL MATRIX

If F49 is equal to 0, then skip to F51.

F50. When you had insertive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every time

__ Don't Know

__ Refuse to Answer

F51. Number of times you had receptive anal intercourse (your partners penis inserted into your anus) with partner 3 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F51 is equal to 0, then skip to instruction before F53.

F52. When you had receptive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every times

__ Don't Know

__ Refuse to Answer

If F52 is equal to 0, then skip to instruction before F53.

SECTION F – SOCIAL MATRIX

If F1 is equal to 3, then skip to instruction before G1.

***READ AND HEARD*: The next set of questions is about your fourth most recent sexual partner in the last year, after you have learned about your HIV positive result.**

F53. What is Partner 4's gender? (Check all that apply)

__ Male

__ Female

__ Transgender

__ Don't Know

__ Refuse to Answer

F54. How old is partner 4?

__ __

97 Don't Know

98 Refuse to Answer

F55. What type of partner is partner 4? (Choose one)

1 Anonymous - Did not know, met for sex, never plan to see again

2 One time - Already knew person, but had sex only once

3 Acquaintance - Had sex more than once but not regularly

4 Friend (you socialize with this person) - Had sex more than once but not regularly

5 Main partner - Your spouse or main sex partner

6 Sex worker - Money or other goods were exchanged for sex

7 Don't Know

8 Refuse to Answer

F56. How would you describe partner 4's race or ethnicity? (Choose one)

1 Caucasian

2 Black

3 Asian

4 Mulatto/Pardo

5 Indian

7 Don't Know

8 Refuse to Answer

If E11 is equal to 0, then skip to F57.

If E11 is equal to 1, then skip to instruction before F58.

F57. Is partner 4 an injection drug user? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

If F53 is equal to 2, then skip to F59.

F58. Is partner 4 a male who has had sex with other male? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

SECTION F – SOCIAL MATRIX

F59. What is partner 4's HIV status? (Choose one)

1 Positive

2 Negative

3 Unknown

8 Refuse to Answer

F60. Where did you first meet partner 4? (Choose one)

01 Bar, cafe, nightclub, restaurant, gym or athletic activity.

02 Sex club, bathhouse

03 Street, park, library, public transportation

04 Parties, clubs, political function or church

05 Internet

06 Dating service, newspaper ads

07 Carnival

08 Work

09 Met some other way

97 Don't Know

98 Refuse to Answer

If F60 is not equal to 9, then skip to instruction before F62.

F61. Specify where you met partner 4:

_____

If B1 is equal to 1 and F53 is equal to 0, then skip to F66.

If B1 is equal to 1 and F53 is equal to 1, then skip to F62.

SECTION F – SOCIAL MATRIX

If B1 is equal to 2 and F53 is equal to 0, then skip to F62.

If B1 is equal to 2 and F53 is equal to 1, then skip to instruction before F70.

F62. Number of times you had vaginal intercourse with partner 4 in past 12 months. (Choose one)

__ none

__ 1 to 3 times.

__ 4 to 10 times.

__ more than 10 times.

__ Don't Know

__ Refuse to Answer

If F62 is equal to 0, then skip to F64.

F63. When you had vaginal sex, how frequently did you use condoms? (Choose one)

__ Never

__ Sometimes.

__ Every time.

__ Don't Know

__ Refuse to Answer

If F63 is equal to 0, then skip to F64.

F64. Number of times you had anal intercourse with partner 4 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F64 is equal to 0, then skip to instruction before F70.

F65. When you had anal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

If F65 is equal to 0, then skip to instruction before F70.

Skip to instruction before F70.

F66. (Ask of Men Only) Number of times you had insertive anal intercourse (your penis inserted into your partner's anus) with partner 4 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F66 is equal to 0, then skip to F68.

F67. When you had insertive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every time

__ Don't Know

__ Refuse to Answer

F68. Number of times you had receptive anal intercourse (your partner's penis inserted into your anus) with partner 4 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

SECTION F – SOCIAL MATRIX

If F68 is equal to 0, then skip to instruction before F70.

F69. When you had receptive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every times

__ Don't Know

__ Refuse to Answer

If F69 is equal to 0, then skip to instruction before F70.

If F1 is equal to 4, then skip to instruction before G1.

***READ AND HEARD*: The next set of questions is about your fifth most recent sexual partner in the last year, after you have learned about your HIV positive result.**

F70. What is Partner 5's gender? (Check all that apply)

__ Male

__ Female

__ Transgender

__ Don't Know

__ Refuse to Answer

F71. How old is partner 5?

__ __

97 Don't Know

98 Refuse to Answer

SECTION F – SOCIAL MATRIX

F72. What type of partner is partner 5? (Choose one)

1 Anonymous - Did not know, met for sex, never plan to see again

2 One time - Already knew person, but had sex only once

3 Acquaintance - Had sex more than once but not regularly

4 Friend (you socialize with this person) - Had sex more than once but not regularly

5 Main partner - Your spouse or main sex partner

6 Sex worker - Money or other goods were exchanged for sex

7 Don't Know

8 Refuse to Answer

F73. How would you describe partner 5's race or ethnicity? (Choose one)

1 Caucasian

2 Black

3 Asian

4 Mulatto/Pardo

5 Indian

7 Don't Know

8 Refuse to Answer

If E11 is equal to 0, then skip to instruction before F75.

If E11 is equal to 1, then skip to instruction before F75.

F74. Is partner 5 an injection drug user? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

If F70 is equal to 2, then skip to F76.

F75. Is partner 5 a male who has had sex with other males? (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

F76. What is partner 5's HIV status? (Choose one)

1 Positive

2 Negative

3 Unknown

8 Refuse to Answer

F77. Where did you first meet partner 5? (Choose one)

01	Bar, cafe, nightclub, restaurant, gym or athletic activity.
02	Sex club, bathhouse
03	Street, park, library, public transportation
04	Parties, clubs, political function or church
05	Internet
06	Dating service, newspaper ads
07	Carnival
08	Work
09	Met some other way
97	Don't Know
98	Refuse to Answer

If F77 is not equal to 9, then skip to instruction before F79.

F78. Specify where you met partner 5:

— —

If B1 is equal to 1 and F70 is equal to 0, then skip to F83.

If B1 is equal to 1 and F70 is equal to 1, then skip to F79.

If B1 is equal to 2 and F70 is equal to 0, then skip to F79.

If B1 is equal to 2 and F70 is equal to 1, then skip to instruction before G1.

If B1 is equal to 1 and F70 is equal to 0, then skip to F83.

If B1 is equal to 1 and F70 is equal to 1, then skip to F79.

SECTION F – SOCIAL MATRIX

If B1 is equal to 2 and F70 is equal to 0, then skip to F79.

If B1 is equal to 2 and F70 is equal to 1, then skip to F79.

F79. Number of times you had vaginal intercourse with partner 5 in past 12 months. (Choose one)

__ none

__ 1 to 3 times.

__ 4 to 10 times.

__ more than 10 times.

__ Don't Know

__ Refuse to Answer

If F79 is equal to 0, then skip to F81.

F80. When you had vaginal sex, how frequently did you use condoms? (Choose one)

__ Never

__ Sometimes.

__ Every time.

__ Don't Know

__ Refuse to Answer

If F80 is equal to 0, then skip to F81.

SECTION F – SOCIAL MATRIX

F81. Number of times you had anal intercourse with partner 5 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F81 is equal to 0, then skip to instruction before G1.

F82. When you had anal sex, how frequently did you use condoms? (Choose one)

__ never

__ sometimes

__ every time

__ Don't Know

__ Refuse to Answer

If F82 is equal to 0, then skip to instruction before G1.

Skip to instruction before G1.

F83. (Ask of Men Only) Number of times you had insertive anal intercourse (your penis inserted into your partner's anus) with partner 5 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F83 is equal to 0, then skip to F85.

F84. When you had insertive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every time

__ Don't Know

__ Refuse to Answer

F85. Number of times you had receptive anal intercourse (your partner's penis inserted into your anus) with partner 5 in past 12 months. (Choose one)

__ none

__ 1 to 3 times

__ 4 to 10 times

__ more than 10 times

__ Don't Know

__ Refuse to Answer

If F85 is equal to 0, then skip to instruction before G1.

F86. When you had receptive anal sex, how frequently did you use condoms? (Choose one)

__ never

__ some times

__ every times

__ Don't Know

__ Refuse to Answer

If F86 is equal to 0, then skip to instruction before G1.

Section G - Medical History

***READ AND HEARD*:** In the next set of questions we will ask about some medical treatments you may have had.

G1. **Since you learned of your HIV test result, have you received a blood transfusion?** (Choose one)

0	No	***Skip to G4***
1	Yes	
7	Don't Know	
8	Refuse to Answer	

G2. **Since you learned of your HIV test result, how many transfusions have you received?**

— —

97	Don't Know
98	Refuse to Answer

G3. **When was the <u>last year</u> you received a transfusion?**

— — — —

9997	Don't Know
9998	Refuse to Answer

G4. **Since you learned of your HIV test result, have you had minor or major medical surgery, tooth extraction, or another dental procedure?** (Choose one)

0	No
1	Yes
7	Don't Know
8	Refuse to Answer

SECTION G – MEDICAL HISTORY

G5. **Since you learned of your HIV test result, have you had endoscopy or colonoscopy?** (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

G6. **Since you learned of your HIV test result, have you taken antiretroviral therapy (ART) ?** (Choose one)

0 No ***Skip to instruction before H1***

1 Yes

7 Don't Know

8 Refuse to Answer

G7. **If yes, in what year did you start taking ART?**

— — — — yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

G8. **Are you currently taking ART?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

9 Not Applicable

SECTION G – MEDICAL HISTORY

G9. **What ART are you currently taking? A list and pictures of available therapies are provided to help you recall.** (Check all that apply)

__ Abacavir

__ Didanosine

__ Estavudine

__ Lamivudine

__ Tenofovir

__ Zidovudine

__ Efavirenz

__ Nevirapine

__ Etravirine

__ Atazanavir

__ Danunavir

__ Fosamprenavir

__ Indinavir

__ Lopinavir

__ Nelfinavir

__ Ritonavir

__ Saquinavir

__ Tipranavir

__ Enfuvintide

__ Raltegravir

__ Don't Know

__ Refuse to Answer

Section H- General Activities or Exposures

***READ AND HEARD*: The next set of questions we will focus on other exposures you may have had.**

H1. **Since you learned of your HIV test result, have you spent three or more nights in jail, prison, or a detention center?** (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

H2. **Since you learned of your HIV test result, have you had acupuncture treatments?** (Choose one)

0 No

1 Yes

7 Don't Know

8 Refuse to Answer

H3. **Since you learned of your HIV test result, have you had a new tattoo or had one re-applied?** (Choose one)

0 No ***Skip to H5***

1 Yes

7 Don't Know

8 Refuse to Answer

SECTION H – GENERAL ACTIVITIES OR EXPOSURES

H4. **Since you learned of your HIV test result, where did you get your most recent tattoo?** (Choose one)

1 Tattoo parlor

2 At home, a friends place, or at parties/raves

3 Jail

4 Other

7 Don't Know

8 Refuse to Answer

H5. **Since you learned of your HIV test result, have you had new ear or body piercings?** (Choose one)

0 No ***Skip to H7***

1 Yes

7 Don't Know

8 Refuse to Answer

H6. **Since you learned of your HIV test result, where did you get your most recent piercing?** (Choose one)

1 Pharmacy or medical clinic

2 Tattoo/piercing parlor

3 At home, a friends place, or at parties/raves

4 Jail

5 Other

7 Don't Know

8 Refuse to Answer

SECTION H – GENERAL ACTIVITIES OR EXPOSURES

H7. **Since you learned of your HIV test result, have you had a manicure or pedicure or had a shave at a barber shop?** (Choose one)

0	No	***Skip to instruction before H9***
1	Yes	
7	Don't Know	
8	Refuse to Answer	

H8. **Since you learned of your HIV test result, how many times have you had manicures or pedicures or shaves at a barbershop?** (Choose one)

1	1 time
2	2 to 5 times
3	5 or more times
7	Don't Know
8	Refuse to Answer

***READ AND HEARD*: Now, we would like to know about any personal contact you have had with persons who either have AIDS or have tested positive for HIV. In each question, please include only family members, personal friends or acquaintances.**

H9. How many people do you personally know who do NOT have AIDS, but have HIV, the virus that causes AIDS? **Please do not include yourself when answering this question** (Choose one)

0	0 (none)
1	1
2	2 to 4
3	5 or more
7	Don't Know
8	Refuse to Answer

SECTION H – GENERAL ACTIVITIES OR EXPOSURES

H10. **How many people do you personally know who currently have AIDS? Please do not include yourself when answering this question.** (Choose one)

0	0 (none)
1	1
2	2 to 4
3	5 or more
7	Don't Know
8	Refuse to Answer

Section I - Counseling and Notification

***READ AND HEARD*: The next set of questions we will focus on Counseling and Notification, since you learned your HIV test result.**

I1. **When did you first learn about your HIV test result? Type month and year**

__ __ / __ __ __ __ mm / yyyy

2097 Don't Know (Year)

2098 Refuse to Answer (Year)

2099 Not Applicable (Year)

I2. **Where did you first learn about your HIV test result?** (Choose one)

0 At the Blood Center

1 At a Counseling and Testing Center (CTA)

2 At a Private lab

3 At a Public lab

4 Other place

7 Don't Know

8 Refuse to Answer

If I2 is not equal to 0, then skip to I4.

I3. **How do you rate your confidence level in the blood bank physician during your HIV counseling and notification?** (Choose one)

0 Very confident

1 Confident

2 Somehow confident

3 Not confident

7 Don't Know

8 Refuse to Answer

I4. **How do you rate the counseling skills of the blood bank physician during your HIV test result notification?** (Choose one)

0 Very Satisfactory

1 Satisfactory

2 Unsatisfactory

3 Very Unsatisfactory

7 Don't Know

8 Refuse to Answer

I5. **How do you rate the importance of the blood bank counseling physician in your decision to seek health care?** (Choose one)

0 Very Important

1 Important

2 Somehow important

3 Not important at all

7 Don't Know

8 Refuse to Answer

I6. **After the blood bank physician notification and counseling, did you go to seek health care somewhere else?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

If I6 is not equal to 1, then skip to I10.

I7. **After the blood bank physician notification and counseling, where did you go to seek health care?** (Choose one)

0 Volunteer Counseling and Testing site

1 Private Hospital

2 Public Hospital

3 My physician's office

4 Other

7 Don't Know

8 Refuse to Answer

If I7 is not equal to 4, then skip to I9.

I8. Please specify other place __

I9. **After the blood bank physician notification and counseling, how long did it take for you to seek health care somewhere else?** (Choose one)

0 Within 2 weeks

1 2 - 4 weeks

2 1 - 3 months

3 4 - 6 months

4 More than 6 months

7 Don't Know

8 Refuse to Answer

I10. **After you learned about your HIV test result, have you disclosed your result to someone else?** (Choose one)

0 No ***Skip to I12***

1 Yes

7 Don't Know

8 Refuse to Answer

SECTION I – COUNSELING AND NOTIFCATION

I11. **To whom have you disclosed your HIV test result?** (Check all that apply)

__ My partner/spouse

__ Best friend

__ Several friends

__ Family

__ Co-worker(s)

__ Priest or other religious leader

__ Health care provider

__ Other

__ Don't Know

__ Refuse to Answer

I12. **What are the reasons for not disclosing your HIV test result?** (Check all that apply)

__ I'm afraid of discrimination

__ I feel ashamed/embarrassed

__ I believe this is my personal/private information

__ Other reason

__ Don't Know

__ Refuse to Answer

If I12 is not equal to 6, then skip to I13.

I12b. **Please specify the other reason**

____

I13. **Have you felt discriminated against because of your HIV test result?** (Choose one)

0	Not at all	***Skip to instruction before J1***
1	A little	
2	Somewhat	
3	A lot	
7	Don't Know	
8	Refuse to Answer	

I14. **Can you tell us more about why you feel discrimination? Did something occur that you felt was discrimination?** (Check all that apply)

__ Have you been discriminated against by coworkers or classmates because of your HIV test result.

__ Someone has made fun of you because of your HIV test result.

__ Someone has offended you because of your HIV test result.

__ You have been harassed because of your HIV test result.

__ All above

__ Other

__ Don't Know

__ Refuse to Answer

Section J- Impact of Your Test Result

READ AND HEARD: **In the following section we are going to ask you some questions related to how you may behave and think, and how others may behave and think in regard to HIV. We understand this is a very sensitive topic. Please read the questions carefully and answer as honestly as you can.**

J1. **In the place where you work are people friends with other people who have HIV?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

J2. **Are you concerned you might give HIV to someone else?** (Choose one)

0 not at all ***Skip to J3***

1 a little

2 a fair amount

3 a great deal

7 Don't Know

8 Refuse to Answer

SECTION J – IMPACT OF YOUR TEST RESULT

J2a. **In what ways are you concerned of transmitting HIV?** (Check all that apply)

__ Using bathrooms, public showers, gyms

__ Shaking hands, touching, hugging people

__ Sharing dishes, glasses, spoons, forks, etc

__ Kissing other people

__ Protected sex (with condoms)

__ Unprotected sex (without condoms)

__ Pregnancy

__ Breastfeeding

__ Other

__ Don't Know

__ Refuse to Answer

If J2a is not equal to 9, then skip to J3.

J2c. **Could you please, specify other ways of transmission?**

_ _

J3. **Do you feel that people avoid you because of your HIV test result?** (Choose one)

0 not at all

1 at little

2 a fair amount

3 a great deal

7 Don't Know

8 Refuse to Answer

J4. **Has anyone forced you to move out of a place you lived because of your HIV test result?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

J5. **Have you been refused housing because people suspect you might have HIV?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

***READ AND HEARD*: Please read the questions carefully and answer as honestly as you can about how you perceive health care workers act towards people who are HIV positive.**

J6. **Has a health care provider made you feel bad because of your HIV test result?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

J7. **Has a health care provider refused to touch you because of your HIV test result?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

SECTION J – IMPACT OF YOUR TEST RESULT

J8. **Have you been refused medical care or denied hospital services because of your HIV test result?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

***READ AND HEARD*: The next set of questions are about your opinions which can help us to make blood transfusion safer.**

J9. **To help us to make blood safer, what would you recommend for improving the donor selection process? Any thoughts or ideas you have are good, please type as much or little as you would like to write.**

_ _

J10. **What could we do to get blood donors to disclose risk behaviors? Any thoughts or ideas you have are good, please type as much or little as you would like to write.**

_ _

J11. **Would you be more comfortable during the donation interview if the blood center staff was:** (Check all that apply)

__ Same sex as you

__ Same age as you

__ Same sexual orientation as you

__ Open minded and accepting; gay friendly

__ More engaged and interactive

__ Other

__ Don't Know

__ Refuse to Answer

SECTION J – IMPACT OF YOUR TEST RESULT

If J11 is not equal to 6, then skip to J13.

J12. **Could you please, specify other**

_ _

J13. **Would you be willing to answer more detailed and specific behavioral risk questions during the donor screening process, if the interview:** (Check all that apply)

__ Took place in a private booth

__ Used an electronic interview (like this one)

__ Gave you more time to answer to the questions

__ Included more explanation of the questions you are asked

__ Other

__ Don't Know

__ Refuse to Answer

If J13 is not equal to 5, then skip to instruction before J15.

J14. **Could you please, specify other?**

_ _

***READ AND HEARD*: The next questions are about any volunteer work or paid work to support individuals living with HIV/AIDS that you are doing or have done since you learned of your HIV test result. Please read carefully and answer as honestly as you can.**

J15. **Since you learned of your HIV test result, have you considered volunteering or working with organizations that provide support or services to individuals living with HIV/AIDS?**

1 Yes

0 No ***Skip to end of questionnaire***

7 Don't Know

8 Refuse to Answer

SECTION J – IMPACT OF YOUR TEST RESULT

J16. **Do you currently do volunteer or paid work with organizations that provide support or services to individuals living with HIV/AIDS?**

1 Yes

0 No ***Skip to J18***

7 Don't Know

8 Refuse to Answer

9 Not Applicable ***Skip to J18***

J17. **What kind of organization are you currently doing volunteer or paid work with?**

_ _

J18. **Would you consider volunteering or doing paid work in the future?**

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

***READ AND HEARD*: Thank you for taking the time to complete this questionnaire. If you have any questions or concerns, please talk to the research assistant or nurse. You can also contact the medical director at our blood bank.**

***READ AND HEARD*: You have finished the questionnaire. From now on, DO NOT touch the screen. Please, talk to the research assistant, the person who assisted you at the beginning of this questionnaire. This assistant will close the screen and acknowledge you for your participation in this study.**

Appendix 4 Aim 2 and 3 Study Invitation Letter

City, <Day> <Month> <Year>.

Dear Sir/Madam

You are being invited to participate in the research project "REDS III: RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY-III-INTERNATIONAL," under the general direction of Dr. Ester Sabino.

You are being invited because you donated blood at this blood bank and because you have participated in previous research at this blood bank. If you agree to participate in this study, you will answer a questionnaire on a computer in a private area. The questions will be related to your behaviors and experiences since your blood donation and participation in our previous research study. It will take around 40 minutes while you are at the blood center to complete all study activities. There are no costs to participate. If you decide to participate, the project will pay you $35 USD (R$ 75)) to offset the amount spent on transportation to the Blood Center, the study site.

This multicenter study is being conducted simultaneously at the following hemocenters: Fundacao Hemope in Recife, Pernambuco; Fundacao Pro Sangue, São Paulo; Fundacao Hemominas in Belo Horizonte, Minas Gerais; Fundacao Hemorio Foundation, Rio de Janeiro. The study is a collaboration with Blood Systems Research Institute in San Francisco, USA.

To learn more or to participate in this research study, please contact us by phone at XXXXX, extension XXX, and ask to speak with XXXXX to schedule an appointment according to your availability. We will also contact you by phone soon to determine if you are interested in participating.

We look forward to your participation.

Sincerely,

Dr. XXXXXXX XXXXXXXXX

Blood Center Site Principal Investigator

E-mail: XXXXXXX@XXXXX.br

Appendix 5 Data capture elements for Aim 1 and Aim 2 of the project

			Used/ Needed For		
#	**English**	**Portuguese**	**Aim 1**	**Aim 2**	**Notes**
1	Donor ID	Doador	X		Unique person ID
2	Donation Date	Data Doação	X		
3	Infectious Disease Marker Tested	Pesquisa	X		Syphilis, HIV, Chagas, HBC, HBV, HCV, HTLV
4	Infectious Disease Marker Result	Res. Doação	X		P = positive; data files would be limited to donors with a positive test result among one of the ID markers tested (above)
5	Number of Letters Sent	Quantidade de Cartas	X		
6	Date of 1st Letter	Data Primeira Carta	X		
7	Trigger for 1st Letter	Motivo do Envio 1° Carta	X		
8	Date 1st Letter Received	Data Recebimento	X		
9	Date 1st Letter Returned	Data Devolução 1° carta	X		
10	Reason for 1st Letter Returned	Motivo Devolução	X		
11	Date of 2nd Letter	Data Envio 2° Carta	X		
12	Trigger for 2nd Letter	Motivo Envio 2° Carta	X		
13	Date 2nd Letter Received	Data Recebimento 2 ° Carta	X		
14	Date 2nd Letter Returned	Data Devolução 2° Carta	X		
15	Reason for 2nd Letter Returned	Motivo Devolucao 2° Carta	X		
16	Date of 3rd Letter	Data Envio 3° Carta	X		
17	Trigger for 3rd Letter	Motivo do Envio 3° Carta	X		
18	Date 3rd Letter Received	Data Recebimento 3° Carta	X		
19	Date 3rd Letter Returned	Data Devolução 3° Carta	X		
20	Reason for 3rd Letter Returned	Motivo Devolução 3° Carta	X		
21	Date of Phone Call	Data da Ligação Telefonica	X		
22	Number of Letters Sent to Non-Deliverable Address	Quantidade Cartas Devolovidas por Endereço Insuficiente	X		
23	2nd Sample Collected	Teve 2° Amostra	X		
24	Date of 2nd Sample	Data da Segunda Amostra	X		
25	Result of 2nd Sample	Resultado Segunda Amostra	X		
26	Date of 3rd Sample	Data 3° Amostra	X		

27	Result of 3rd Sample	Resultado 3° Amostra	X		
28	Date of Counseling	Data Aconselhamento	X		Date donor returned to blood bank to learn of testing results
29	Sex	Sexo	X		
30	Age at the time of donation	Idade	X		
31	City/Municipality	Municipio	X		
32	Current Address	Endereco atual	X		
33	Zip Code	CEP	X		
34	Race/Ethnicity	Cor	X		
35	First Name	Nome		X	
36	Last Name	Sobrenome		X	
37	Birth date	Data de nascimento		X	
38	City of Birth	Cidade de Nascimento		X	
39	Unified Health System Number (SUS number)	Numero SUS		X	
38	Financial Person Registration	Cadastro de Pessoas Físicas (CPF)		X	Analogous to SSN in the US
40	General Registration (RG)	Registro Geral		X	
41	Other unique person IDs as required by MOH			X	
42	Mother's FULL Name	Nome Completo da Mae		X	