Attachment 4 – Informed Consents
OMB Number: TBD

1. **Draft Informed Consent for Focus Groups**

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Blood Donation Rules Opinion Study (Blood DROPS)

Research studies include only people who choose to take part. This is a research study about the views of men who have sex with men on blood donation. The study researchers are Dr. Brian Custer, PhD, MPH from Blood Systems Research Institute and Nicolas Sheon, Ph.D. from the Center for AIDS Prevention Studies at the University of California, San Francisco. If you have any questions, you may contact the researchers using the information below.

Why is this study being done?
The purpose of this study is to learn more about people's views on blood donation deferral policies.

Am I eligible to take this survey?
You are being asked to take part in this study because you know or believe that you are HIV negative, 18 years or older, speak English, and live near one of our focus group sites the United States. You may only participate in one focus group. In addition, only one member of a household is eligible to participate in the focus group.

Who pays for this study?
The U.S. Federal Government is paying for this study through research funds allocated to the National Heart, Lung, and Blood Institute of the National Institutes of Health.

How many people will take part in this study?
About 50-60 people will take part in this focus group study.

What will happen if I take part in this research study?
If you agree to be in this study, you will be asked to participate in a focus group about blood donation policies and how they impact men who have sex with men. The focus group will be video and audio recorded so that we can transcribe and study and analyze the recorded conversation in detail.

Are there any risks to me or to my privacy?
Some of the focus group discussion questions may make you feel uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

Your name and contact information was collected during recruitment in order to schedule the focus group. This contact information will be destroyed after you have participated in the focus group. No names will be used during the focus group. Instead each participant will be assigned a

unique pseudonym that will be used instead of names.

As a focus group member, you agree not to reveal the identity of participants or the content of anything discussed during the focus groups with anyone outside of the focus group you participated in. Participation in any research involves the risk of loss of privacy. Complete confidentiality cannot be guaranteed. You must decide for yourself what to share with the focus group, given that focus group members might talk about you or what you say outside the group.

The video recording of the focus group will be encrypted and stored on a password-protected computer. Only study staff analyzing the data will have access to the encrypted video. Any names or identifiers will be bleeped from the video soundtrack and no identifiers or names will be used in the transcripts or discussions of the study among the researchers. In order to conduct future secondary analyses, we will retain the video data until December 31, 2015, after which it will be destroyed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. On rare occasions, research records have been subpoenaed by a court. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- UCSF's Committee on Human Research
- The National Heart, Lung, and Blood Institute

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

> Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

Can I say "No," or stop being in the study?
Yes. You do not have to participate in the focus group and can decide to stop at any time.

Are there benefits to taking part in the study?
There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand blood donor policies are understood by and affect potential donors.

Who can answer my questions about the study?
You can talk with the study researcher about any questions, concerns, or complaints you have about this study. Contact the study researchers: Dr. Brian Custer at 415-901-0756 or Dr. Nicolas Sheon at 415-597-9109. You may also email us at blood@ucsf.edu

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Office of the Committee on Human Research by telephone at 415-476-1814 or by email at CHR@ucsf.edu.

What are the costs of taking part in this study?
You will not be charged for any of the study procedures.

Will I be paid for taking part in this study?
In return for your time and effort for traveling to and participating in the focus group, you will receive a $50 Amazon.com gift card at the end of the focus group.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

CONSENT
You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent

2. Draft Informed Consent for Web-based Screening Questions for MSM and Blood Donor Surveys

Blood Donation Rules Opinion Study (Blood DROPS)

Welcome
Researchers at the Blood Systems Research Institute and University of California San Francisco's Center for AIDS Prevention Studies are conducting a study about blood donation. This study explores men's views about blood donation policies that are designed to screen out donors with a history of male-male sexual contact.

The Principle Investigators for this study are Dr. Brian Custer, PhD, MPH and Dr. Nicolas Sheon, PhD.

For more information about the study, you may contact the study team.

email: blood@ucsf.edu
phone: (415) 597-9109

Please be sure to read the privacy statement, eligibility requirements, and survey instructions below before you continue. Failure to do so may result in your inability to successfully complete the survey.
If you are eligible and complete the survey, we will email you a $10 Amazon.com Gift Code within 30 days. The survey takes approximately 20 minutes to complete.

PRIVACY
If you click the "Next Page" button at the bottom of this page to proceed with participation in the survey, specific electronic information will be automatically collected from your web browser and Internet connection. None of this information will be used to personally identify you. If you do not continue to the next page of the survey, none of this information will be collected from you. This allows you to decide if you want to share the information with the study researchers. The information includes:

- *IP (internet Protocol) address*: Your computer uses an IP address every time you connect to the Internet. It is a unique number that is used to identify computers on a network, so that data requested (such as web pages) can be sent to the computer.
- *General information* about the web browser, type of device (Dell computer, iPad, etc.) and operating system you are using. This information is sent automatically by most web browsers when you visit any web site.
- The *"referrer,"*, which is information passed along by your web browser that references the web site you linked from to reach this survey.

ELIGIBILITY

The survey will begin by asking a number of questions to determine if you qualify to participate in the study.

You may complete only one survey. In addition, only a single member of a household is eligible to take the survey. Additional criteria are explained later in the survey's consent document.

If you are accessing this survey using an "anonymous web proxy" that masks your true IP address, or any other method that alters information about your Internet connection, then you are ineligible to participate in this study.

INSTRUCTIONS FOR COMPLETING THE SURVEY

If you want to return to a previous page of the survey, click the "Previous Page" button located at the bottom of the survey web page. Do not use the "Back" button in the toolbar of your web browser.

You may exit the survey at any time and then return later to complete the survey, but only by clicking on the box titled *"Click here to save your progress and continue the survey later,"* which appears at the bottom of every survey page. When you return to the survey web site, the questions will begin exactly where you left off. We ask that you please complete the survey within three days of beginning it.

3. **Draft Consent for Web-based Surveys for Blood Donation Rules Opinion Study (Blood DROPS)**

Congratulations! Based on your answers, you are eligible to take our survey.
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Blood Donation Rules Opinion Study (Blood DROPS)

Research studies include only people who choose to take part. This is a research study about the views of men who have sex with men on blood donation. The study researchers are Dr. Brian Custer, PhD, MPH from Blood Systems Research Institute and Nicolas Sheon, Ph.D. from the Center for AIDS Prevention Studies at the University of California, San Francisco. If you have any questions, you may contact the researchers using the information below.
Why is this study being done? The purpose of this study is to learn more about people's views on blood donation deferral policies.

Am I eligible to take this survey? You are being asked to take part in this study because you have either never been tested for HBV, HCV, or HIV, or have not tested positive or any of these viruses, are age 18 or older, live in one of the research sites, have access to the Internet, and able to complete the survey using a computer located in the U.S. You may complete only one survey. In addition, only one member of a household is eligible to take the survey, and only one email account may be used to receive compensation for completing the survey.

Who pays for this study? The U.S. Federal Government is paying for this study through research funds allocated to the National Heart, Lung, and Blood Institute of the National Institutes of Health.

How many people will take part in this study? About 5000 people will take part in this study.

What will happen if I take part in this research study? If you agree to be in this study, you will be asked to complete a web-based survey. You will be asked basic demographic questions, some questions about your sexual history that are typically used to screen potential blood donors, and questions to elicit your opinions about blood donation policies that currently screen out donors with a history of male-male sexual contact. It will take you approximately 20 minutes to complete the survey.

Are there any risks to me or to my privacy? Some of the survey questions may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question. All of your responses are confidential.

We will do our best to protect the information we collect from you. Any information that could be used to identify you will be kept secure. We will store the survey data, encrypted on a password-protected computer. Only a small number of researchers will have direct access to completed surveys. If this study is published or presented at scientific meetings, names or other information that might identify you will not be used.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal,

administrative, legislative, or other proceedings. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

Certain types of information will be automatically collected from your web browser and Internet connection. As explained earlier in the survey, this information includes:

- *IP (Internet Protocol) address:* Your computer uses an IP address every time you connect to the Internet. It is a unique number that is used to identify computers on a network, so that data requested (such as web pages) can be sent to the computer.
- *General information about your web browser, type of device (such as a Dell computer, iPad, etc.) and operating system you are using.* Web browsers automatically send this information when you visit any web site.
- *The "referring web site,"* which is information passed along by your web browser indicating the web site you linked from to reach this survey.

None of this information will be used to personally identify you, and researchers will only analyze the information for determining the validity of survey data. This information will be collected only for the stated reason and not used later for any other reason. The researchers will not try to access your computer, or gather any other information aside from your answers to survey questions and the electronic information already described above.

IP address information will be deleted and destroyed immediately after the researchers complete their analysis of the survey project.

Are there any eligibility requirements for how I access the online survey? Yes. If you access the survey using a service called an "anonymous web proxy" that conceals or falsifies your true IP address, or use any other electronic method that alters information about your Internet connection, you are not eligible to complete this survey. Although some individuals make legitimate use of web proxies to protect their online information, we require you to temporarily forgo this minimal loss of privacy to complete the survey. The purpose of this requirement is not to identify individuals, but rather to block respondents from completing multiple surveys, granting researchers the ability to detect and prevent behavior that may negatively affect the validity of the study.

Can I say "No," or stop being in the study? Yes. You do not have to complete the survey and can decide to stop at any time.

Are there benefits to taking part in the study? There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand blood donor policies and how they affect potential donors.
Who can answer my questions about the study? You can talk with the study researchers about any questions, concerns, or complaints you have about this study. Contact Dr. Brian Custer at 415-901-0756 or Dr. Nicolas Sheon at 415-597-9109. You may also email us at blood@ucsf.edu

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research of the University of California, San Francisco at 415-476-1814.

Will I be paid for taking part in this study? In return for your time and effort for completing the survey, you will receive a $10 Amazon.com gift code within 30 days. Upon completion of the survey, you will be asked to provide an email address so the Amazon.com gift code can be sent to you.

We validate all Amazon.com gift codes before distributing them. If you encounter difficulty redeeming your code, you must resolve the problem with Amazon.com's customer assistance. Contact information for Amazon.com gift code support is included with the code you will receive by email. Amazon.com is not a sponsor, affiliate, or endorser of this study in any way.

If you use a service such as an "anonymous web proxy" to change or conceal your true IP address (as defined above), or use any other method that alters information about your Internet connection, you will not receive an Amazon.com gift code even if you complete the survey, because you do not meet the eligibility criteria for the study as described above.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point.
11) I have read and understand this consent form.
( ) I wish to participate in this study.
( ) I do not wish to participate in this study

4. **Draft Informed Consent for Qualitative Telephone Interviews for Blood Donation Rules Opinion Study (Blood DROPS)**

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Blood Donation Rules Opinion Study (Blood DROPS)

Research studies include only people who choose to take part. This study explores men's views about blood donation policies that are designed to screen out donors with a history of male-male sexual contact. This study is being conducted as part of the Recipient Epidemiology and Donor Evaluation Study (REDS-III) research program, which has centers located in California, Connecticut, Pennsylvania, and Wisconsin. REDS-III is run by the National Heart, Lung, and Blood Institute of the National Institutes of Health. The study researchers are Brian Custer, PhD, MPH from Blood Systems Research Institute (San Francisco, CA) and Nicolas Sheon, Ph.D. from the Center for AIDS Prevention Studies at the University of California, San Francisco. If you have any questions, you may contact the researchers using the information below.

Why is this study being done?
The purpose of this study is to learn more about people's views on blood donation deferral policies.

Am I eligible to be interviewed?
You are being asked to take part in this study because you know or believe that you are HIV negative, 18 years or older, speak English, and live near one of our research sites the United States.

Who pays for this study?
The U.S. Federal Government is paying for this study through research funds allocated to the National Heart, Lung, and Blood Institute of the National Institutes of Health.

How many people will take part in this study?
About 15-20 people will take part in one-on-one qualitative interviews by telephone to further explore the study topic in more detail.

What will happen if I take part in this research study?
If you agree to be in this study, you will be asked questions about blood donation policies and how they impact men who have sex with men. The telephone conversations will be audio recorded so that we can transcribe and study the recorded conversations in detail.

Are there any risks to me or to my privacy?
Some of the questions may make you feel uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

Your email address was collected during recruitment for an online survey you participated in

which is how we have been able to contact you to ask you to participate in this follow-up study. This contact information will be destroyed after study is complete and whether you choose to participate or not. In addition, each participant who completes the interview will be assigned a unique pseudonym that will be used instead of names.

Participation in any research involves the risk of loss of privacy. Complete confidentiality cannot be guaranteed.

The audio recording of each interview will be encrypted and stored on a password-protected computer. Only study staff analyzing the data will have access to the encrypted audio. Any names or identifiers will be bleeped from the soundtrack and no identifiers or names will be used in the transcripts or discussions of the study among the researchers. In order to conduct future secondary analyses, we will retain the audio data until December 31, 2015, after which it will be destroyed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. On rare occasions, research records have been subpoenaed by a court. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- UCSF's Committee on Human Research
- The National Heart, Lung, and Blood Institute

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

> Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

Can I say "No," or stop being in the study?
Yes. You do not have to participate in the telephone interview and can decide to stop at any time.

Are there benefits to taking part in the study?
There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand blood donor policies are understood by and affect potential donors.

Who can answer my questions about the study?

You can talk with the study researchers about any questions, concerns, or complaints you have about this study. Contact the study researchers: Dr. Brian Custer at 415-901-0756 or Dr. Nicolas Sheon at 415-597-9109. You may also email us at blood@ucsf.edu

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Office of the Committee on Human Research by telephone at 415-476-1814 or by email at CHR@ucsf.edu.

What are the costs of taking part in this study?
You will not be charged for any of the study procedures.

Will I be paid for taking part in this study?
In return for your time and effort for traveling to and participating in the interview, you will receive a $50 Amazon.com gift card at the end of the interview.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____
Date Participant's Signature for Consent

_____ _____
Date Person Obtaining Consent