

**Attachment 8: Protocol**  
**OMB Number: TBD**

Concept Synopsis and Study Schema

The current policy for blood donation in the US with respect to men who have sex with men (MSM) is that any man who discloses having had sex with another man since 1977 (MSM77) is deferred indefinitely from donating. Any potential change to the MSM policy for blood donation requires additional data that is not currently available. One study from Sweden sought to directly assess the MSM and blood donation by surveying the MSM population. In this 2007 study, 19% of 334 MSM who responded reported donating blood at some time since 1985. Another study conducted in 2009-2010 from the UK reported that 10.6% of 1028 MSM who completed a survey had donated blood even though they were ineligible according to the existing lifetime deferral policy in the UK, and 2.5% of sexually active MSM had donated within the previous year. The UK policy has now been changed and a 1-year deferral for sexually active MSM has been adopted. In the US, motivating factors and compliance or not with the current policy are unstudied aspects of the larger issue. In the proposed study, data directly relevant to this issue will be collected through the assessment of motivations for blood donation in the MSM population using focus group participants as key informants. Surveys of MSM and of male blood donors in the communities where Recipient Epidemiology and Donor Evaluation Study (REDS-III) blood centers are located will be conducted to estimate the prevalence of compliance and non-compliance with the current policy using web-based surveys, and to assess intended compliance with a potentially modified MSM policy. A final component of the project will seek to conduct telephone interviews of persons who report both MSM and blood donation to determine primary drivers for MSM who actually do donate blood. These studies will provide a currently unavailable assessment of this topic in the US and can also help to guide improved communication strategies with potential donors.

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#### **4.1. Background and Significance**

The current policy for blood donation in the US with respect to men who have sex with men (MSM) is that any man who discloses having had sex with another man since 1977 (MSM77) is deferred indefinitely from donating. However, data from donors who have tested disease marker positive and were interviewed regarding potential risk factors suggest that some individuals continue to donate blood without disclosing MSM activity in contravention of the policy. Surveillance studies of risk factors in donors who have donated HIV positive units in the US from the late 1980s found MSM behavior to be a risk factor for 56% of male donors.<sup>1</sup> Studies that have not been reported in the peer-reviewed literature from research conducted in the 1990s continued to find that MSM behavior remains a common risk factor for donating an HIV positive unit. In addition, as part of the Retrovirus Epidemiology Donor Study (REDS), when anonymously surveyed by paper and pencil mailed surveys, 1.2% of male blood donors reported MSM behavior.<sup>2</sup> Potential change to the current MSM policy for blood donation requires additional data that is not available. Speculative analyses have been conducted but do not directly address important considerations related to this policy such as the current level of compliance (in the MSM population) and non-compliance (in the blood donor population).

The reasons underlying why MSM donate blood regardless of the FDA policy are undoubtedly complex. Possible reasons for the failure of some donors to self-defer may include the following:<sup>3,4</sup> (1) denial about risk behaviors; (2) a personal belief that one's own blood is safe for others because MSM activity was remote and a person otherwise "feels fine"; (3) knowledge that all blood is tested for HIV and that testing will (presumably) identify any potential risks to transfusion recipients; (4) failure to read or fully comprehend the screening questions or associated instructions; (5) desire to obtain HIV test results irrespective of the potential risk presented to recipients of donated blood; or (6) a belief that the policy is discriminatory and that disobedience is therefore acceptable from the donor's perspective.

One study from Sweden sought to directly assess the prevalence of MSM who donate blood by surveying a convenience sample of the MSM population. In this 2007 study, 19% of 334 MSM who responded to a survey that was included in a monthly publication targeted to the Lesbian, Gay, Bisexual and Transgender (LGBT) community reported donating blood at least one-time since 1985. The authors suggested that MSM donors may be motivated by perceived discrimination, particularly younger MSM. MSM learning about the lifetime deferral policy for MSM (men who report MSM activity since 1985 in the case of Sweden) while also learning that heterosexual donors with HIV risks are deferred from donating for only a one-year period, may be prompted to "donate blood in protest against the prohibition because they believe the rule to be discriminatory."<sup>5</sup> Of the survey respondents who reported donating blood, 58% (34) admitted giving blood after their first time having sex with men, despite the fact that all but one of them knew the rule that MSM may not give blood. Furthermore, most of these donors had donated blood on more than one occasion, and four of the respondents admitted to donating blood during the previous 12 months. If these men are representative of all MSM in Sweden, then the number of active male blood donors who are MSM was estimated to be close to 1,000. The researchers reported that younger men and men in the larger metropolitan areas tended to give blood to a greater extent than older men and men outside the big cities. 68% of all respondents answered that they believe that some MSM give blood in spite of the prohibition. Another common justification was that all blood is tested anyway, so the prohibition was unnecessary. The younger men, to a greater extent than older men, were of the opinion that the current rule with a total exclusion for MSM should be changed.

Placed within the context of the number of total blood donors in Sweden who donate in a given year (approximately 200,000 per year of which 54% (~108,000) are males [pers. com. Rut Norda] and extending these finding to the US this would suggest that as many as 0.9% (~45,000) of all US male donors may be MSM. However, this estimate requires a significant number of untested or unverified assumptions. In addition, there are several aspects of the study from Sweden that suggest it may not be appropriate to generalize the findings to other settings. First, the study remains unpublished in the peer-reviewed literature, making assessment of some of the methods used difficult. Second, even though the project was conducted in partnership with an LGBT organization, the response rate was under 35%.

The topic of MSM and donation has received new attention in the last 5 years as many jurisdictions have sought to re-examine the relevance of indefinite deferral of MSM from donation<sup>6</sup>. Analyses examining the risks associated with the current policy and modified policies have been conducted in many settings. Few of these analyses have been published in the peer-reviewed literature. In France, as in the US, MSM are indefinitely deferred from donating blood, but a recent study showed that the current MSM policy may be ineffective.<sup>7</sup> Pillonel and colleagues estimated the fraction of current risk of HIV that could be attributed to MSM under the indefinite deferral policy, and then constructed a mathematical model that used behavioral and epidemiological survey data to assess the impact of a new strategy. Under the modeled strategy MSM would be deferred if they reported more than one sexual partner within the last 12 months. The authors suggest that some MSM may not properly self-report their sexual activity and abstain from blood donation because they feel that the policy is discriminatory. This suggests that while the intent of MSM deferral policies is to reduce the risk of HIV, the reality may be that because some donors may intentionally not disclose risk, HIV risk is incrementally increased. Overall, the authors concluded that a change in policy with relaxed MSM donor eligibility criteria may increase the risk of HIV by a very small amount. However, they suggested that this finding does not take into account the possibility that men in this community could find the new policy more acceptable, more accurately reporting their risk or abstaining from blood donation, thus actually reducing the risk.

Recent publications from the United Kingdom have reported what are likely the only population-based assessment of non-compliance with a similar restriction on blood donation for the MSM population and estimates of modification of the policy as a result. The first study conducted in 2009-2010, used a population-based household survey design followed by qualitative interviews. Following a screening question to assess MSM behavior, the survey included a 20 question module relating to blood donation, sexual practice, and sexual identity. 1028 men completed the blood donation module. In the study, Grenfell and colleagues report that 10.6% of MSM in the population in Britain have donated blood while ineligible under the existing policy, and that 2.5% have donated within a 1-year period before blood donation.<sup>8</sup> Davison and colleagues report that if prevalence is the only factor affected by a reduced deferral in the UK, then the increased risk of HIV is probably negligible, but the impact of a change depends on compliance; if this stays the same or worsens, the risk is expected to increase because of more incident infections in MSM who donate blood.<sup>9</sup> Recently the UK regulators modified the previous virtually indefinite deferral to a deferral of 1-year duration for recent MSM sexual contact and the National Blood Service has adopted the new policy, meaning the modified acceptance criteria for MSM will start in November 2011.<sup>10, 11</sup>

Within a broader context of current infectious risks associated with transfusion, Vamvakas has conducted a systematic review of the risks of known and emerging transfusion-transmitted infections (TTIs) if the current lifetime blood donation deferral for MSM was reduced to 1 or 5 years compared to

the risks from the currently accepted practice of using pooled whole-blood-derived (rather than single-donor) platelets.<sup>12</sup> The number of HIV, hepatitis B virus, or hepatitis C virus TTIs from reducing the MSM deferral to 1 year was estimated, respectively, at 0.88, 2.94, or 66.9. Numbers which are much more than 10 times smaller than the risk of bacterial infection from currently used pooled platelets. If additional infections such as herpesvirus-8 (HHV-8) transmissions attributable to MSM are considered, any purported increased risk remains far smaller than the current risk of transfusion-associated sepsis from pooled platelets. As would be expected, modification of the current MSM deferral to a 5 year deferral would represent lower risk than a 1 year deferral. In conclusion, Vamvakas states that acceptance of MSM as blood donors after 1 or 5 years' abstinence may result in a postulated increase in risk that is so much smaller than currently tolerated transfusion risks and so small in absolute terms that the ethical question of fairness to the MSM group justifies the change in policy.

At the June 2010 meeting, the Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability was asked to consider several aspects of this topic. The Advisory Committee's statement on the current policy and recommendations included the following:<sup>13</sup>

The HHS's Advisory Committee on Blood Safety and Availability (the Committee or ACBSA) is sensitive to the blood system and broader societal issues related to the current deferral policy for males who have had sex with another man (MSM) even one time since 1977. Whereas we believe that the current donor deferral policies are suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations, we find that currently available scientific data are inadequate to support change to a specific alternative policy; therefore, until further evaluation, the committee recommends that the current indefinite deferral for men who have had sex with another man even one time since 1977 not be changed at the present time. To develop and validate candidate alternative [MSM and blood donation] policies, we recommend research in the following areas:

1. Validate modifications to the donor questionnaire that would better differentiate low versus high risk MSM and heterosexuals, including studies to investigate Transfusion Transmitted Infectious Disease (TTID) and Sexual Transmitted Disease (STD) markers in potential donor subsets;
2. Establish ongoing national hemovigilance program for TTID markers in blood donors linked to analysis of demographic, behavioral, and other risk factors:
  - Obtain a baseline on prevalence and incidence of TTIDs,
  - Characterize risk in different donor subgroups (e.g., younger age), and
  - Use above characteristics for continuous quality improvement of the donor deferral process;
3. Determine the feasibility of donor pre-testing to limit risk while characterizing donors who might be recruited under modified eligibility criteria;
4. Investigate the impact of revised donor criteria on the global availability of plasma products;
5. Evaluation of data from other countries that have changed their high risk donor evaluation programs, including MSM; and
6. Periodic reassessment of transfusion safety including consideration of multiple and cumulative blood product exposures to recipients.

## Significance

While many scientists and ethicists have expressed opinions in support or against modification of current MSM policy for blood donation<sup>14-25</sup> there is a paucity of data that directly addresses important aspects of this policy debate. Motivating factors and compliance or not with the policy or a modified policy by MSM and current blood donors is an important and as yet unstudied aspect of the larger issue. The proposed study will build off the studies conducted in Sweden and UK and will collect directly relevant information on this topic by assessing motivations for blood donation in the MSM population using key informants and by estimating the prevalence of compliance and non-compliance with the current policy.

## **4.2. Summary of Study Objectives, Aims and Research Questions**

### **Aim 1 Focus Groups of MSM population**

#### Aim 1 Primary Objective

To assess opinions about and common themes within the MSM population with respect to blood donation and the current MSM77 policy.

Research Question 1.1: Within a population of self-identified MSM in the US, what common themes can be identified regarding knowledge and opinions of current blood donation eligibility, and would opinions (including self-reported intended compliance) change if the MSM77 policy were changed to a deferral of a defined shorter duration?

#### Aim 1 Secondary Objective

To use the focus groups as key informants to select proper venues for recruiting MSM into the Aim 2.1 survey.

Research Question 1.2: Where are the venues for advertising the Aim 2 survey in each of the four cities?

### **Aim 2 Surveys to Estimate the Prevalence of Compliance and Non-compliance**

#### Aim 2 Primary Objectives

Aim 2.1 - To assess compliance in the MSM population with the current MSM77 blood donation policy

Aim 2.2 - To assess non-compliance in the blood donor population with the current MSM77 blood donation policy.

We intend to survey two groups using an instrument that includes common content in order to assess compliance and non-compliance with the MSM77 policy. Our goal is to have the duplicate content on each of the surveys in order to maximize the comparability of the responses. Surveys will be conducted using online or internet-based techniques and currently available software (SurveyGizmo, [www.surveygizmo.com](http://www.surveygizmo.com)). Our survey populations and research questions are:

2.1) A confidential survey of the MSM community that will provide better estimates of compliance and non-compliance with the MSM77 policy.

Research Question 2.1: Within a population of MSM who are surveyed confidentially, what is the frequency of self-disclosed compliance with the current MSM77 policy?

2.2) A confidential survey of male blood donors to find out how frequently persons with MSM77 behavior are donating blood.

Research Question 2.2: Within a population of US blood donors who are surveyed confidentially, what is the frequency of self-disclosed non-compliance with the current MSM77 policy?

### **Aim 3: Qualitative Interviews of Persons who report MSM and blood donation**

#### Aim 3 Primary Objective

To assess actual motivations for donating in the population of self-identified MSM who are active blood donors in the US?

Participants from the four cities who report actual blood donation or the intention to donate will be asked to participate in a qualitative telephone interview that will include content similar to that of the Aim 1 Focus Groups.

Research Question 3.1: Within a population of self-identified MSM who are blood donors in the US, what common themes can be identified regarding motivations for donating blood?



## **Aim 1 Focus Groups of MSM population**

### 4.3. Aim 1 Study Population

Due to budgetary limitations on the study design, a population-based sample of MSM from the four cities for the focus groups is beyond the scope of this study. We will therefore use a purposive sampling frame that will sample participants who are likely to have relevant insights on the topic. Because the goal of Aim 1 is to explore the views of MSM on the topic of deferral, the ideal participants would be either (1) MSM who have tried to donate blood but were denied the opportunity due to their MSM behavior, or (2) MSM who have donated blood in spite of unreported MSM behavior or sexually transmitted infections (STI). Because the population of MSM who have donated or tried to donate is a small and hidden population, we will also broaden the sample to include other HIV negative MSM to better understand perceptions of donor deferral policy, what changes they would suggest to the current donor screening process, and how HIV negative MSM evaluate their own risk as potential blood donors.

#### 4.3.1 Inclusion Criteria

Self-identified MSM who are over 18 and

- a. have donated blood, or
- b. attempted to donate blood, or
- c. believe or know themselves to be HIV, HCV, and HBV negative and have no history of intravenous drug use (IVDU).
- d. live in the geographic area of one of the four study sites.

#### 4.3.2 Exclusion Criteria

Men who know they are HIV positive or who are intravenous drug users and therefore would not be allowed to donate even if the MSM deferral policy was modified.

We will also exclude women and children (<18 years of age) from the focus groups.

### 4.4. Study Enrollment

We will conduct two focus groups in each of the four cities. Each group will have 6-8 participants for a total of approximately 56 participants.

#### 4.4.1 Screening/Recruitment

Eligibility screening for the focus groups will be done using a brief online screening questionnaire on SurveyGizmo. Eligible participants will be asked for their phone number and email address and contacted by study staff about the focus group time and location. Participant contact information will be stored securely in SurveyGizmo and only study personnel will have access to the data. All participant contact information will be deleted from SurveyGizmo immediately after the focus groups have been conducted. Survey Gizmo is certified in both the HIPAA Privacy Rule and the Security Rule provisions.

This means they meet the guidelines from a privacy perspective as well as a security perspective. More information on Survey Gizmo's HIPAA compliance can be found online at: <http://www.surveygizmo.com/survey-blog/online-survey-hipaa-safe-harbor-certification/>

### Venue-based Recruitment

We will seek to recruit focus group participants by advertising the study in media and locations where MSM congregate in the four areas where we will conduct focus groups (San Francisco, Milwaukee, Pittsburgh, and New Haven, Connecticut). These will vary by city due to the differences in size and diversification of gay venues by subculture in San Francisco versus the other metro areas. For example, we will place an advertisement in the Hartford Gay and Lesbian Health Collective, MPower CT, CT Gay Men's Chorus programs and on mats for their monthly bingo nights; and we will advertise through gay sports leagues, such as the Saturday Softball League in Milwaukee or the Steel City Softball league in Pittsburgh. We will also contact organizations representing gay parents, local seminaries, LGBT student organizations, LGBT religious organizations, and local chapters of National organizations advocating for equal rights for LGBT populations. By using existing networks of discussion boards, organizational newsletters, classifieds, and word of mouth, we will recruit focus group participants and then ask those participants about other ways to recruit MSM for the survey. Because each ad and venue palm card will have a specific link to the screening survey, we will be able to monitor how many eligible participants were recruited from the various locations and networks. This will help us identify the most effective means to recruit the web survey sample so we can target our efforts effectively.

To monitor the progress and geographic distribution of focus group and survey recruitment efforts, we will have recruiters use their cell phones to take geo-tagged photographs of flyers they post so that we can monitor the dates and locations of recruitment efforts using Google Photo (Picassa) and Google Maps service. These maps will be supplemented with information derived from focus groups participants about other venues to recruit MSM for the surveys.

#### 4.4.2 Stratification or Randomization

Not Applicable

#### 4.5. Interventions

Not Applicable

#### 4.6. Measurements

### Focus Group Discussion Topics

To address our first research question, we will assess general awareness and understanding of the eligibility screening and deferral process for blood donors. Then we will assess understanding of a few key deferrals, including sexual risk factor deferral and perhaps deferral for travel to malaria endemic areas. The purpose in inquiring on these topics is to assess whether the key informants are aware that the intent of donor deferral is to reduce potential risks to blood recipients.

In order to develop a broader understanding of the donor selection process, we may role play the screening questionnaire and distribute the associated instructions during the focus group so that participants can get a sense of what the deferral process is like and imagine themselves in the position of being a blood donor. The shared experience of the focus group eligibility screening questions, which are similar to those asked of potential male blood donors, will contribute to the focus group discussion of the ethics of non-disclosure of MSM risk in order to donate blood.

#### *Focus Group Content Domains*

The following questions explore participant views on HIV testing as they relate to risk questions and risk perception.

MSM perspectives on blood donation eligibility rules.

Accuracy of MSM's understanding of the policy/rules.

Perceptions of the rationale behind the rules.

Perceptions of the fairness of the rules.

How should sexual contact between men be defined and asked about to determine donor eligibility?  
How should the questions be asked, e.g. by person or by computer?

Perceptions of MSM's motivations for non-compliance with the rules and for donating blood.

Potential changes to the eligibility rules.

Suggested changes to eligibility rules from focus group participants.

Review of changes to MSM eligibility rules in UK, Sweden, Australia, New Zealand and Spain.

If any of these changes were adopted in the US, how would they affect compliance and blood safety?

Suggestions of venues for recruitment of local MSM for the survey?

How has this discussion changed your views on blood donation?

#### 4.5.1 Preparation

We will conduct one pilot focus group in San Francisco of not more than 8 participants to assess focus group procedures and content. Complete analysis of this group will not be conducted, but broad findings in terms of recruiting subjects and themes identified in the pilot focus group will be used to refine the approach used for the actual focus groups.

#### 4.5.2 Administration

We plan to conduct the focus groups in July or August of 2012. The focus groups in each city will be conducted within a contiguous two week period of time.

#### 4.5.3 Control Population

Not Applicable.

#### 4.6.1 Schedule of Measurement

The most logical place to hold the focus groups in other REDS-III cities is at the local LGBT centers and rent a room at each of these facilities. LGBT centers are typically located in neighborhoods that are accessible by public transportation and safe for LGBT participants to be at night. We will conduct 8 focus groups (2 in each of the four cities) with 6 to 8 participants per group. Focus groups will be conducted contiguously in order to minimize the amount of travel, i.e. go from San Francisco -> Milwaukee -> Connecticut -> Pittsburgh -> San Francisco over an approximately two week period.

#### 4.6.2 Definitions

Not Applicable

#### 4.6.3 Assessment and Measurement Procedures

A total of 8 focus groups with approximately 6-8 participants per group will be conducted. Investigators at the Center for AIDS Prevention Studies (CAPS) have found that this number of participants per group is more conducive to an in depth discussion and sharing of personal views with less simultaneous cross-talk. Larger groups are more difficult to manage and only 6-8 of the participants speak regularly anyway. The focus groups will elicit rich narrative descriptions about the social norms and acceptability of blood donation by MSM. While it is unlikely that participants will admit to actually donating blood, we will ask them how they learned about the MSM77 policy, explore their reactions upon learning about it and to speculate on the motivations of men who donate blood despite having had sex with other men.

**Recruitment and sampling for Focus Groups:** Flyers will be posted at local LGBT organizations, gyms, cafes, and support groups in each of the four cities. We will also advertise in local gay weekly papers. Interested participants will be directed to a web survey which will screen them for eligibility (MSM who have tested negative for disease markers (HIV, HBV, HCV) in the last 12 months) or who believe themselves to be negative for these markers, or MSM with blood donation experience. We will conduct a San Francisco focus group as a pilot for the formal focus groups to be conducted in each of the four cities. We will use theoretical sampling to further define our sampling criteria in the other three cities based on research questions that emerge from the analysis of the San Francisco groups. For example, we may try to recruit participants within a certain age range, or those who are active in gay rights organizations to explore the impact of these variables on their views on MSM77. This flexible approach to qualitative sampling is purposive and will help us recruit a diverse sample to discover as many relevant thematic domains as possible.

#### 4.6.4 Specimen collection procedures

Not Applicable

#### 4.6.5 Special test procedures if required

Not Applicable

#### 4.7. Survey Considerations and OMB Requirements

See Human Subjects section which covers this topic for the entire study.

#### 4.8. Data Management

We recognize the sensitivity of video data and the added risk of loss of privacy over audio data alone. While digital audio may be sufficient for individual interviews, analysis of focus groups requires attention to non-verbal behavior, direction of gaze, and the physical performance of social identities and status. It is therefore imperative that we be able to see who talks when, to whom, and how others react in order to make sense of the focus group data. However, because video data are necessary for our research questions, and indeed have become the norm in many types of qualitative research, we have devised a comprehensive data security protocol that addresses the primary risks of data loss and secure storage.

Video data will be recorded onto digital media (SDHC card) using a portable video recorder (Kodak Zi8) that records directly into QuickTime h.264 format and can be connected by cable to a professional quality microphone in the center of the focus group table to capture better sound than typical video cameras. Using this format avoids the need for a digital video tape (mini DV) which must be compressed and converted to a format that is compatible with Transana prior to analysis. Because the Kodak Zi8 uses SDHC rather than MiniDV or miniDVD, the video data can be easily transferred from the recorder and stored in an encrypted volume that is then stored on a secure computer or burned on a DVD in a locked cabinet. At the conclusion of each focus group, the video data will be transferred via USB cable to an encrypted volume created on a laptop computer using TrueCrypt software. TrueCrypt software is free and can be used in conjunction with other encryption software designed to encrypt access to the computer itself. Dr. Sheon has produced an online guide for using TrueCrypt at <http://www.palmpal.org/trucrypt.pdf>. TrueCrypt creates an encrypted volume on a computer hard drive using AES-256-bit encryption. The encrypted volume can only be opened using a password. Only study personnel will have access to this password. In case of hard drive failure, backup copies of the focus group video data will be stored for safekeeping as encrypted volumes on burned onto DVD-R discs that will be kept in a locked cabinet at the UCSF Center for AIDS Prevention Studies. The encrypted volume will be opened (mounted) only when it is being analyzed using Transana. At all other times, the encrypted volumes containing the data will remain closed (dismounted) and thereby encrypted. Because the video data are stored in an encrypted format, the risk of unauthorized access is eliminated. Even if a laptop computer or DVD-R containing the video is stolen, the encrypted volume would prevent access to the data contained therein.

Only Dr. Sheon and the transcriptionist will have access to the encrypted volume. The transcriptionist, Paul Garton, is experienced in focus group and video transcription. He has been trained to use Transana software and follows a strict data management and security protocol developed by Dr. Sheon. Because Mr. Garton works off of the UCSF campus, we will use the following steps in order to ensure data security during the transcription process. The encrypted volume containing the focus group video will be transmitted to Mr. Garton using his YouSendIt service account. Dr. Sheon will upload an encrypted volume containing video using Mr. Garton's YouSendIt portal on his web site: [transcriptcoop.com](http://transcriptcoop.com). Once the encrypted volume has been uploaded to the YouSendIt data center, Mr Garton will receive an email that a new file has been sent, Mr. Garton will click on a link in the email which downloads the file to his

computer from one of YouSendIt's data centers. In order to protect data integrity during file transfer, YouSendIt employs the Secure Socket Layer (SSL) that implements industry-standard, 128-bit SSL encryption deployed using Class 3 certificates and Server-Gated Cryptography (SGC). A description of YouSendIt's security protocols is provided at <http://www.yousendit.com/cms/security>. Once Mr. Garton has downloaded the file to his computer, he will enter the password provided by Dr. Sheon to mount the encrypted volume so that he can transcribe the video using Transana software. In this way, we use multiple layers of redundant encryption, email authentication, and passwords for both Truecrypt and Transana to secure the video and audio data sent to the transcriptionist. Once Mr. Garton has finished transcribing the data, he uploads the transcript onto the Transana database and then adds time codes at each new speaker turn in order to synchronize the video with the transcript. Once the transcript has been timecoded, he will then dismount the encrypted volume and delete it from his computer and the YouSendIt server.

Transana software, which we will use to analyze the video data from the focus group and individual interviews, provides an additional layer of security. To access the study database, Transana software requires a user name and password to access annotations such as codes and transcripts of the data which are stored on the Transana server at the Center for AIDS Prevention Studies. These user credentials are administered by Dr. Sheon. All annotations will be anonymized and will not contain any personal identifiers. To access the study database on Transana, users must also have a copy of the video or audio data available, and to do that, they would need to have TrueCrypt and know the encryption password. Unless the encrypted volume is mounted, attempts to open a transcript or video in Transana will return an error message saying that the media in question could not be found.

#### 4.9. Statistical Considerations

Aim 1 is exclusively qualitative research.

##### 4.9.1 Hypothesized outcome rate and smallest difference to detect w/high statistical power

Not Applicable

##### 4.9.2 Sample size and power

Not Applicable

##### 4.9.3 Participant Incentives

Participants will be offered a \$50 incentive for participation as the focus groups in Aim 1 as an electronic gift certificate to Amazon.com.

Participant Incentives/Reimbursement: The procedures around petty cash and providing incentives can be very complex. Using Amazon electronic certificates (or from an equivalent company) sent to each participant's email address solves a major administrative problem and saves us a lot of personnel time and accounting issues.

##### 4.9.4 Analytic Approach

The focus groups will be video recorded for analysis using methods Dr. Sheon developed for other studies with HIV positive men and women. The advantages of video over audio recording are that video enables the researcher to distinguish individual speakers during cross talk, which is impossible with audio-only recordings of focus groups. Being able to see who is talking when, and who they are speaking to.

**Analysis of the Focus Group Data:** Focus Groups will be video recorded and analyzed using innovative methods Dr. Sheon devised for another study of HIV-positive men and women's views on cancer research that was approved by the UCSF Committee on Human Research (UCSF's IRB). Analysis of the focus groups will begin immediately following the focus group as the researchers present during the focus group will debrief, review the salient points, dynamics and unexpected findings from the discussion. Video and audio recordings of the focus groups sessions and post-group debriefing sessions will be systematically analyzed using Transana software designed for the transcription and analysis of digital video and audio data.<sup>26</sup> Systematic analysis of focus groups requires the ability to distinguish among several simultaneous speakers, to identify whether the next speaker is new or the same as the previous turn.<sup>27</sup> Focus group data is particularly challenging to transcribe and analyze because participants often speak simultaneously and use non-verbal cues such as chuckling and shifting their gaze to express agreement and disagreement with the current speaker. For this reason, video will be used to capture these important aspects of the interaction.

Focus groups allow us to observe the social processes that shape individual behavior and beliefs by showing how these change depending on the context of the discussion.<sup>26-29</sup> Our innovative approach will enable us to observe how participants espouse various stances on the issues discussed over the course of the discussion and how these evolve in response to views expressed by others. In addition, video enables us to pay attention to non-verbal behavior, direction of gaze, and the physical performance of group membership, such as agreement with other speakers through nodding and other non-verbal cues. Video provides access to other performative aspects such as hair styles, fashion, gesture, posture, physical proximity and facial expressions. A key research question in the proposed study is how membership in the gay community relates to views on blood donation deferral policies. Video data are essential to observe the performative and demographic characteristics of focus group participants and correlate them with their verbal contributions to the discussion.

**Transcription, segmentation, and coding of the video:** Transana allows data analysis to begin prior to transcription by coding the audio and video itself. Our first analytic pass of the data will select and code the most analytically relevant segments of the focus groups for systematic transcription and thereby reduce transcription time and costs. These segments will be transcribed by a transcriptionist who has been trained to insert Transana time codes at each speaker change while transcribing. These time codes synchronize the transcript to the video much like subtitles are synchronized to the dialogue in films and facilitate coding of who is speaking on a particular theme. Codes will be based on themes that emerge from the data. We will double code two of the focus groups in order to reach consensus on the initial code list. Intercoder agreement will be measured using sequence maps which are designed to help visualize agreement in the length of coded segments as well as concurrency of codes.

**Sequence Maps to visualize patterns in the focus group data.** Dr. Sheon has worked with the Transana software developer on numerous new features that facilitate sequential analysis of digital video/audio files. One feature, called "Sequence Maps" uses colored bars along the timeline of the video to facilitate

the visual analysis of patterns of discussion such as who spoke when, for how long, and on what theme. Once speaker turns are coded by theme and participant, Transana sequence maps will help us visualize broad patterns of agreement and disagreement among participants over the course of the entire focus group and across focus groups. This will enable us to determine whether certain themes or beliefs are widely shared among the group, or idiosyncratic among certain participants. For example, a common pattern in focus groups is that a view expressed by one participant is rejected by others as non-normative, and this is displayed by a silence or shift in topic in the next turn. Alternately, a view may be embraced and elaborated on by the group in subsequent turns. In this way, the focus groups provide insight into the process of social construction of attitudes and beliefs. We therefore expect to encounter considerable ambivalence about donor deferral. We will therefore be able to observe how participants' views change during the focus groups as they encounter new arguments for and against the MSM77 policy. Being able to track these shifts by specific participants over the course of the focus group will help us to identify how these arguments arise and are deployed within group dynamics. New or unexpected themes identified in the focus groups will be explored in subsequent focus groups and, where appropriate, included in the surveys. The focus groups will enable us to identify particularly rich descriptions that will be useful for a more in-depth understanding of the motivations for blood donation among this population.



## **Aim 2 Surveys to Estimate the Prevalence of Compliance and Non-compliance**

### **Restatement of Aim 2 Study Objectives**

We intend to survey two groups using an instrument that includes common content in order to assess compliance and non-compliance with the MSM77 policy. Our goal is to have the duplicate content on each of the surveys in order to maximize the comparability of the responses. However, it is unlikely that the content can be identical because of the need to tailor specific questions for each of the groups we would like to survey. Surveys will be conducted using online or internet-based techniques and currently available software (SurveyGizmo, [www.surveygizmo.com](http://www.surveygizmo.com)). Our proposed survey populations and research questions are:

1) A confidential survey of the MSM community that will provide better estimates of compliance and non-compliance with the MSM77 policy.

Research Question 2.1: Within a population of MSM who are confidentially surveyed, what is the frequency of self-disclosed compliance with the current MSM77 policy?

2) A confidential survey of blood donors to find out how frequently persons with MSM77 behavior are engaging in blood donation.

Research Question 2.2: Within a population of US blood donors who are confidentially surveyed, what is the frequency of self-disclosed non-compliance with the current MSM77 policy?

### 5.3.1 Inclusion Criteria

Aim 2.1 – Self-identified MSM who are 18 years of age or older.

Aim 2.2 – Self-identified male blood donors who are 18 year of age or older

### 5.3.2 Exclusion Criteria

Females will be excluded from all aims of the study because females are not included in the current definition of MSM or the MSM77 blood donation policy.

While we will seek to exclude women from the survey, we recognize that online surveys could be completed by women. For that reason we have developed content that will be specific to persons who define their sex as female and choose to complete the survey.

### 5.4. Study Enrollment

Although the MSM population has been well defined in San Francisco, it is less known in the other three cities. Using a time and place sampling frame, we will advertise and recruit for the survey using palm cards distributed by locally-based recruiters and HIV prevention outreach workers at venues identified as frequented by HIV negative gay men in the Aim 1 focus groups. Budget limitations do not allow for a true population-based sampling strategy, and thus we are limited in the potential representativeness and are proposing a convenience sample. By conducting an internet survey, our sample will be restricted

to participants who have access to the Internet. This sampling strategy will also not be able to over-recruit minority participants.

#### 5.4.1 Screening/Recruitment

A population-based sample of MSM from the four cities for either the focus groups is beyond the scope of this study. We will also seek to obtain a sample of male donors, but similarly are limited in that it will not be a probability sample. Respondents will have to self-select to complete the web-based survey.

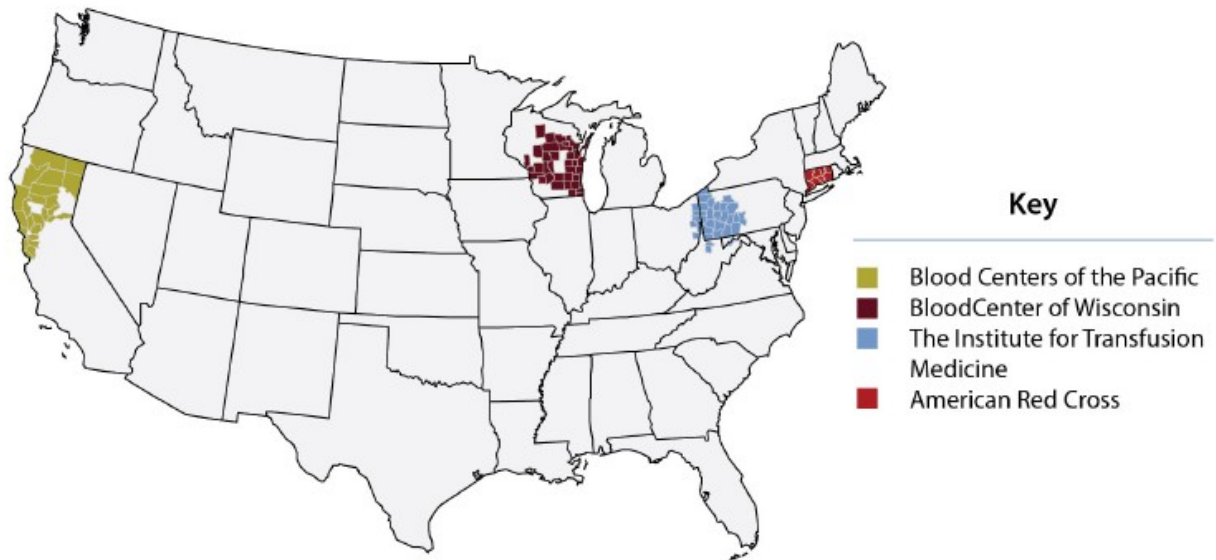
##### Aim 2.1: Survey of MSM

In order to achieve study enrollment and maximize exposure of the MSM population to the study, we will have to advertise for the study and direct potential participants to the study. This will require coordinated outreach efforts in each of the four REDS-III geographic areas. The outreach will take the form of venue-based, time-space recruiting<sup>30,31</sup> (places and times where populations of interest congregate) that will direct potential participants to the Internet survey. Venues will be selected for maximum impact both on the general population of MSM as well as specific populations (e.g., ethnic minorities) in order to maximize diversity.

##### Aim 2.2: Survey of Blood Donors

We will invite persons to participate and will use the same methods for recruiting and sampling. However, the invitation will be different and the venue-based, time-space recruiting will focus on blood centers or donor rolls from the REDS-III centers. The preferred approach for recruitment is to distribute survey links via donor rolls for recent donors (for example, who donated within the last year) as opposed to specifically recruiting donors who are at the blood center donating on a given day. However, we recognize the challenges this may represent for the REDS-III blood centers, and so plan to recruit survey participants at fixed and mobile donation sites. The counties that comprise the catchment areas for blood donors for the REDS-III study are provided in the figure below.

## REDS-III Domestic Blood Center Catchment Areas by County



### 5.4.2 Stratification or Randomization

Not Applicable

### 5.5. Interventions

Not Applicable

#### 5.5.1 Preparation

Not Applicable

#### 5.5.2 Administration

Aim 2.1 and 2.2 surveys will be initiated simultaneously. We plan to conduct the surveys during a 3-month period in October through December of 2013

Geographic specificity of the MSM survey: This is a limitation of web surveys and the key to overcoming this limitation is that recruitment must be highly focused and preferably done by postal mailing or flyers to LGBT organizations, or in person by handing out palm cards with a specific link for that recruitment location. The first survey question will ask participants to provide a detailed description of where they

learned about the study. Participants who report learning about the survey from an online source, will be classified as suspicious in the analysis. We will conduct daily searches on search engines for survey links posted online. Responses will be monitored in real time for spikes in the number of responses from a particular survey link associated with a particular venue flyer or ad placement. These links can be inactivated immediately in the event that a link is posted on the Internet and attracts the attention of professional survey takers. By using several survey links per city, deactivating one link will minimize the impact on recruitment from the other links.

Suspicious responses will be assessed for signs of satisficing, i.e. straight lining, internally inconsistent responses, and short response times. The timing of responses will also be examined to identify potential repeat respondents. For example, participants who attempt to complete several surveys in quick succession but are initially disqualified by the screening questions and change their responses until they are eligible can be detected by examining the timing of consecutive responses.

In SurveyGizmo, repeat survey respondents are automatically prevented from accessing the survey from the same IP address. Survey Gizmo's duplicate IP blocking feature is designed to prevent repeat responses from the same computer by storing IP address of past respondents, however, there are ways around this. For example, it is possible to obtain a new IP address by simply turning the modem off and on before revisiting the survey site. However, because the modem is still using the same Internet Service Provider, the new IP address is typically very similar to the previous one. Consecutive responses from a similar IP addresses, i.e. addresses that differ only in the last group of numbers, will be flagged as suspicious. Another way around Survey Gizmo's duplicate IP blocking is to use a proxy service that changes the IP address associated with your browser. We will use third party proxy IP detection services such as MaxMind.com to screen out respondents using an IP address associated with a proxy service. Typically, proxy IP numbers do not match the geographic location claimed by the survey respondent. Non-US IP addresses will be screened out as ineligible. While it is impossible to prevent determined repeat responders, there are ways to minimize the impact of repeat responders on the survey budget and to identify them so that their responses can be discarded from the analysis. Participants will be notified on the initial page of the survey that only one response is allowed and that if they continue on to the screening questions, their IP address will be logged by Survey Gizmo and if they are using a proxy service, they will not be paid for their participation. This notification will deter repeat responders and those that are detected will not be paid for repeat responses.

### 5.5.3 Control Population

Not Applicable

## 5.6. Measurement

The draft survey content is provided as Appendix 1. The survey covers three broad content domains:

- 1) Sexual history
- 2) Blood donation history
- 3) Opinions about current and modified MSM blood donation policies

### 5.6.1 Schedule of Measurement

The survey will be completed by each participant only one time.

## 5.6.2 Definitions

Not Applicable

## 5.6.3 Assessment and Measurement Procedures

Surveys will be entirely electronic. Instrument content may be modified by the research team based on the findings from Aim 1. The previous study from Sweden provides the basis for the content that we have developed for the US survey instrument (see Appendix 1). This study will also rely on the survey instrument content of previous REDS research, but will expand the content to focus on the specific issue of MSM and possible policy changes regarding donor eligibility. The final content of the survey will be developed with CAPS experts. The survey will be internet-based and will also use SurveyGizmo.

### Survey Instruments

**Programming Time:** The ease of use with web surveys is an important advantage. It is very easy to learn how to manage the application and make changes, and this in turn allows for robust but responsive version control. On web surveys, changes are updated on every survey immediately.

In addition, research groups have reported that the Internet offers valuable opportunities for conducting behavioral surveillance among MSM because it reaches some men who may not otherwise be accessed in the community.<sup>32</sup> The potential ability to access groups that are difficult to reach is a critical advantage for the proposed methodology.

### Experience with Internet-based Surveys

CAPS investigators and other groups in San Francisco have significant experience using web-based survey methodologies, including studies focused on the MSM population.<sup>33</sup> Existing publications on web survey administration describe custom web surveys developed by the researchers and the problems they encountered with repeat responders.<sup>34</sup> We are proposing to use SurveyGizmo, which we have extensive experience with. A current study that Dr. Sheon is a Co-Principal Investigator on is Investigating Motivations for Participation in Anal Cancer Prevention Trials (IMPACT) which is a survey of HIV positive men and women in 20 cities in the US and Canada. This study is using SurveyGizmo and has implemented a number of techniques to detect and deter repeat respondents that have been approved by the UCSF IRB. Since July 2011, the IMPACT survey has recruited 200 (half the total sample of 400) valid participants from 13 of the 20 cities and recruitment is ongoing.

## 5.6.4 Specimen collection procedures

Not Applicable

## 5.6.5 Special test procedures if required

**Real Time Monitoring:** Researchers can see the surveys coming in even as they are still being completed. This allows for monitoring recruitment efforts and to adjust aspects of the sampling if necessary. For

example, quotas (when the sampling frame is understood) can be set for certain demographic characteristics for participation and once achieved recruitment efforts can be re-focused by further modification of enrollment allowances to achieve participation by other groups. In this study we do not have a good understanding of the sampling frame. The primary role of real time monitoring will be to reduce the risk that cheaters could bias the results of the surveys by taking the surveys multiple times.

#### 5.7. Survey Considerations and OMB Requirements

See Human Subjects Section that covers this topic for the entire study.

#### 5.8. Data Management

##### **Web Survey and Privacy of Participant Data**

Internet subjects' privacy concerns are typically related to three issues:

- 1) disclosure of information by the researchers to others outside the study;
- 2) use of electronic information to gather additional information without the subject's knowledge or consent, and
- 3) electronic breach of security allowing access of confidential information to unrelated third parties.

Plans to minimize any potential for risk and addressing these three issues are described below, respectively. In addition, an umbrella Certificate of Confidentiality covering all REDS-III activities will be in place.

**1)** As with any other research, the potential for disclosure of personal and private information provided to the researcher may make potential participants wary or concerned. The consent forms will provide participants with advance notice of what data we will be collecting from their internet browser and the measures we will take to protect their confidentiality. These methods include: University-approved encryption methods and other methods to physically and electronically secure data, collecting only the minimum amount of information necessary, that the study would be otherwise impracticable without the information, the researchers will never disclose this information to anyone outside the research team, and the data will be destroyed as soon as possible after the survey project has been completed (within one year). The data will be collected only for the stated purpose and not used subsequently for any other purpose.

Simply posting a privacy policy behind a Web link, which is the norm for other web sites, is not enough given that users might not take the time or effort to inform themselves. We will use a proactive approach that provides the language of pre-notification about privacy on the welcome page's introductory language for the web survey and focus group screener, above and before the button they must click to proceed.

In addition, the welcome page will include an email address to contact the study coordinator, and a link to UCSF's web site. Both end in "ucsf.edu." Research shows that Internet research subjects are much more trusting of established, legitimate institutions such as universities, and public entities such as government organizations over private, for-profit enterprise.

**2)** In only extremely rare cases is an individual's identity directly associated with an IP address in

publicly available directories of IP address assignments. If this should occur, the researcher will never collect, record, or maintain any personally identifying information. No attempts will be made to “reverse engineer” or otherwise trace an IP address to any individual.

Information about the type of web browser and operating system used by a survey respondent cannot be used to identify an individual, although the combination of data elements from this information can be used to create an anonymous, unique identifier that may be used to detect repeat respondents.

The survey respondent will be reassured that the researchers will not attempt to remotely access their computer, or gather any other information aside from the survey respondent’s survey answers and electronic information already described.

**3)** Survey respondent IP addresses will be collected and temporarily stored by SurveyGizmo, the web survey service we are using. Survey Gizmo is fully HIPAA compliant, and uses a number of University-approved protocols to secure the transmission of data over the web, such as “SSL”. Unlike many other online web survey services, SurveyGizmo has the ability to “scrub” (irreversibly erase and destroy) any and all data from their highly secured storage immediately upon the researchers’ request. SurveyGizmo’s official policy is that none of their employees will personally access or view any of the individual data collected. The service only accesses this information by way of software-driven automation to calculate aggregated information for reports.

Respondents will complete the survey using a web-based interface on a computer or smart phone of their choosing. SurveyGizmo is certified in both the HIPAA Privacy Rule and the Security Rule provisions. This means they meet the guidelines from a privacy perspective as well as a security perspective.

UCSF has initiated and is currently in the process of finalizing a HIPAA Business Associate Agreement (BAA) with SurveyGizmo, in coordination with UCSF’s Business Contracts Unit. Once this agreement is finalized, it will apply for all UCSF projects using SurveyGizmo.

### **Aim 2.1: Survey of Members of MSM Community**

Completion of the focus groups will be followed by administration of cross-sectional surveys to collect data on compliance and non-compliance. Data will be collected using internet-based survey instruments. We will provide secure links for the study that will only be assessable to the persons invited to participate in the study.

Use of an internet-based survey tool raises concerns about privacy protection for the research subjects as well as repeated participation by the same respondent. Recent research has shown that younger people are more willing to complete internet versus paper-and-pencil surveys, and that disclosure of stigmatizing or socially-sensitive behaviors is actually higher for internet versus paper-and-pencil surveys, perhaps because of the lack of physical connection to the survey responses when completed by computer. Work from Germany has shown the utility of using internet-based surveys to meet the challenges of obtaining representative data for populations that may be “hidden” or difficult to reach.<sup>35</sup> Moreover, using internet-based survey methods reduces costs of managing the data, is easy for respondents to use, and also allows respondents to participate from the privacy of their own computer or smartphone rather than travel to a research center.<sup>36</sup> Thus, using internet-based surveys will allow us to enroll a larger number of respondents than we might otherwise be able to.

Internet-based surveys do have attendant methodological issues to address.<sup>37, 38</sup> The requirement of Internet access in order to participate in the study tends to select for higher socioeconomic status individuals. However, research has shown such individuals are more likely to be potential blood donors<sup>39</sup> and the increasing use of smart phones has widened access to the Internet (i.e., a desktop or laptop computer is no longer necessary to complete online surveys). Nevertheless, access to the Internet is unequal across individuals and unknown for any given individual, as will be access to (knowledge of) the study itself. Given these unknowns plus self-selection for participation, the results will not reflect a probability sample, nor given the absence of Census data on MSM, can these results be evaluated for representativeness. Thus, although we can define the target population for Aim 2.1 as the MSM community in each of the areas where REDS-III blood centers are geographically located, the survey can only be viewed as a convenience sample of that target population.

## 5.9. Statistical Considerations

### 5.9.1 Hypothesized outcome rate and smallest difference to detect w/high statistical power

The study is intended to estimate the frequency of compliance and non-compliance with the current MSM77 blood donor policy. As such, there is not a specific hypothesis that is being tested.

### 5.9.2 Sample size and power

#### *Sample size and power*

The best data to inform sample size and power calculations comes from the study conducted in Sweden. These data do not directly address sample size or power. In a sample of 334 MSM from a study conducted in 2007, 63 (19%) reported having donated blood since a deferral on MSM donation was adopted in 1985 in that country. In order to estimate the compliance and non-compliance with the MSM policy with sufficient precision based on 95% confidence interval of +/- 2% and assuming an MSM population of 115,700 in the REDS-III study locations<sup>40</sup> we will need a MSM survey sample of 1600 respondents (400 per location) to estimate a previous donation history of 19% with a 95%CI of 17 – 21% for the overall sample and 15 – 23% for each location. If the actual prevalence of non-compliance is lower, then the obtained precision will be greater (i.e., confidence intervals will be narrower). If prevalence is higher, then precision is reduced slightly, but maximum widths (if prevalence is 50%) would be only 5 percentage points for the overall estimate (16.5 – 21.5%) and 10 percentage points within location (14 – 24%).

Similarly if the projections from the Swedish study applied to the population of blood donors in that country are ascribed to the US, we would expect 45,000 donors to report MSM behavior if the entire donor base in the country could be anonymously surveyed. Existing data report that 1.2% of donating males in 1998 were MSM who misrepresented their eligibility (MSM since 1977) and should have self-deferred.<sup>2</sup> A sample of 3200 male blood donors (800 per location) will be sufficient to determine a prevalence of undisclosed MSM behavior in donors of 1.2% with a 95% CI of 0.85 – 1.64% (0.57 – 2.22% within location).

### 5.9.3 Participant Incentives



### *Participation Incentives*

Each participant in either Aim 2 survey will be offered the same incentive for participation; a \$10 online gift certificate. The Aim 2.1 enrollment target is 1,600 respondents (400 in each REDS-III community) and for Aim 2.2 is 3,200 respondents (800 in each REDS-III blood center).

Participant Incentives/Reimbursement: The procedures around petty cash and providing incentives can be very complex. Using Amazon electronic certificates (or from an equivalent company) sent to each participant's email address solves a major administrative problem and saves us a lot of personnel time and accounting issues.

### 5.9.4 Analysis

Analyses will be primarily descriptive. We will report the frequency of responses for each of the questions. In addition we will stratify responses according to age, as it is expected that age (18 to 35, and >35 years) will be related to not only the prevalence of compliance or non-compliance but also to motivating factors for blood donation and interest expressed in donating if the current MSM77 policy was modified

The goal is to estimate the prevalence of blood donation in a sample of MSM in each of the four cities and similarly the proportion of MSM behavior in recent donors.

### **Aim 3: Confidential Qualitative Interviews with Persons with who report MSM and blood donation**

#### Restatement of Aim 3 Study Objectives

We would like to use the outcome of the surveys from participants to identify a group of individuals who are both MSM and recent blood donors to directly assess motivations for giving blood. Survey participants from the four cities who report actual blood donation or the intention to donate will be contacted by email and invited to participate in a 60 minute telephone interview.

Research Question 3.1: Within a population of self-identified MSM who are blood donors in the US, what common themes can be identified regarding motivations for donating blood?

#### 6.3.1 Inclusion Criteria

Self-identified MSM who are over 18 and have donated blood, completed either the Aim 2.1 or Aim 2.2 survey and who have accepted our invitation to participate in a follow-up telephone interview.

#### 6.3.2 Exclusion Criteria

All persons who do not meet the inclusion criteria for this aim.

### 6.4. Study Enrollment or Specimen Procurement

Eligible participants for this aim will be invited by email to participate. All survey participants will be asked to provide their email to receive their \$10 Amazon gift code. Those participants who report blood

donation will be sent a message by email to call Dr. Sheon to set up a telephone interview for which they will be paid \$50.

#### 6.4.1 Screening/Recruitment

Potential participants will be selected based on having participated in the online surveys in Aim 2.1 and 2.2 if the participant provided a valid email address to which the participation incentive was delivered. This in combination with responses obtained from the survey will be used to create a list of eligible subjects. Given the sensitive nature of the topic, we do not anticipate that many participants will call. We expect to interview at most 20 participants for Aim 3.

#### 6.4.2 Stratification or Randomization

Not Applicable

#### 6.5. Interventions

Not Applicable

##### 6.5.1 Preparation

Not Applicable

##### 6.5.2 Administration

The interviews will be conducted by Dr. Sheon who has extensive experience interviewing MSM about HIV testing and creating a safe and secure space for participants to articulate sensitive information such as concerns they may have had with their counselor or the test clinic. During these interviews, participants often disclosed HIV risk they had not disclosed to the HIV test counselor conducting a standardized risk assessment. While telephone interviews limit access to body language and other non-verbal cues available in face-to-face interviews, a major advantage of telephone interviews is that they can be conducted in a private place (e.g. the participant's home) at a mutually convenient time. Unlike focus groups, participants are able to provide a longer narrative of their experience and are more likely to discuss sensitive issues one on one than in a group setting.

##### 6.5.3 Control Population

Not Applicable

#### 6.6. Measurement

Telephone interviews will be audio recorded for transcription and thematic analysis using Transana software. The topics discussed will be similar to the focus groups in Aim 1, but will include additional questions about specific blood donation experiences, motivations for donation, and questions about sexual orientation and blood donation.

Follow-up Interview Content Domains

Warm up question: What was it like taking the survey?

Blood donation experiences.

Describe last donation experience in detail.

Motivations leading up to first donation experience.

How have reasons for donating changed over time?

Aspects of past donation that made you more or less likely to donate again.

Describe a time when you were denied opportunity to donate.

MSM donors perspectives on blood donation eligibility rules.

Accuracy of understanding of the policy/rules.

Perceptions of the rationale behind the rules?

Perceptions of the fairness of the rules?

How should sexual contact between men be defined and asked about to determine donor eligibility?

How should the questions be asked, e.g. by person or by computer?

Perceptions of MSM's motivations for non-compliance with the rules and for donating blood.

Potential changes to the eligibility rules.

Suggested changes to eligibility rules from focus group participants.

Review of changes to MSM eligibility rules in UK, Sweden, Australia, New Zealand and Spain.

If any of these changes were adopted in the US, how would they affect compliance and blood safety?

Explore relationship between sexual identification/orientation and views on blood donation?

How important to you are the rules around MSM's eligibility for blood donation?

How has this discussion changed your views on blood donation?

#### 6.6.1 Schedule of Measurement

We anticipate that it may take some time to schedule the interview so we will initiate contact with the participant as soon as possible after eligible survey participants (i.e. MSM and blood donor) complete the survey.

#### 6.6.2 Definitions (as appropriate)

Not Applicable

### 6.6.3 Assessment and Measurement Procedures

Analysis and interpretation techniques will be the same as those used in Aim 1 except that we will be analyzing audio recordings of telephone interviews instead of video recordings of the focus group discussions.

### 6.6.4 Specimen collection procedures

Not Applicable

### 6.6.5 Special test procedures if required

Not Applicable

### 6.7. Survey Considerations and OMB Requirements

See Human Subjects section for entire study.

### 6.8. Data Management

Audio recordings will be in mp3 format and stored in an encrypted volume on Dr. Sheon's password protected computer. We will use the same data security measures outlined for the transcription and analysis of the video data in Aim 1.

### 6.9. Statistical Considerations

#### 6.9.1 Hypothesized outcome rate and smallest difference to detect w/high statistical power

Aim 3 is entirely qualitative in nature and no hypotheses are being tested

#### 6.9.2 Sample size and power

We do not think it will be easy to identify many study participants who are eligible and willing to participate in the qualitative interviews. For that reason we anticipate interviewing about 15-20 participants for Aim 3.

#### 6.9.3 Participant Incentives

These participants will be offered the same incentive for participation as the focus groups in Aim 1; \$50 online gift certificate. Up to 20 persons from Aim 2 may be identified and if contacted by email will to participate on subsequent confidential online focus group.

#### 6.9.4 Analytic Approach

Analysis and interpretation techniques will be the same as those used in Aim 1. Please see similar section in Aim 1 for specific details.



## 7. Limitations and Alternative Approaches

### Sampling:

The focus groups will be conducted in four metropolitan areas that may not have high levels of race/ethnicity diversity. We recognize this limitation, but are uncertain if this is a critical issue for the goals of the focus groups as blood donors tend to be white<sup>41</sup> and are believed to have generally higher socio-economic status including access to the Internet. For the surveys, by using an internet-based option, we hope to maximize participations such that in analysis we may be able to report results by race/ethnicity.

Reporting bias: The Aim 1 focus groups will be moderated by an experienced moderator who is a gay man in order to fully elicit an open and honest discussion and opinions from MSM participants. We do not believe the responses will reflect bias or socially-desirable answers.

Confounding of survey responses by education level, socioeconomic status and race ethnicity is expected. These variables will be measured, and controlled for using multivariable analysis if we have sufficient sample size to be able to do as part of the Aim surveys.

Further consideration of the appropriateness of internet-based surveys is necessary. Internet surveys often have a better response rate than mailed surveys. However, because this specific instrument will include questions about MSM and blood donation it may be viewed as too risky to do this study as a web questionnaire. Ensuring protection of privacy and honesty of reporting MSM behaviors are of primary importance. To ensure participant privacy, SurveyGizmo will only use IP address information to prevent repeat responses from the same respondent. Participants who do not wish to share their everyday email address with the study researchers can set up a free temporary email account for use with the study. This email would be used to receive their gift code payment for completing the survey and will be the email address we use to contact them for the follow-up interview if they are eligible. This way participant confidentiality will be maintained. The web survey service, SurveyGizmo, is fully HIPAA compliant and will use SSL encryption technology to ensure that participant responses cannot be intercepted, traced, or associated with any identifying information. Respondents may have doubts about whether the web questionnaire is totally confidential. However, alternative approaches, such as a mailed survey, a telephone survey (CATI), or an in person computer assisted survey (CASI) would be less confidential as well as cost prohibitive.

## **8. Human Subjects**

All human subjects and other approval requirements for this study will be met before the study can begin. A certificate of confidentiality from NHLBI that covers REDS-III study activities will be obtained to prevent the blood centers or study investigators from being legally compelled to release information reported by study participants.

Participating in the survey is optional and is not a condition for future blood donation. Donors may refuse participation with no consequences for not participating.

Aim 1 requires written informed consent to allow us to record audio and video of participants.

Aim 2 participants will assent and will indicate consent by completing the survey questionnaire.

Aim 3 will obtain verbal consent that will be document by audio recording at the start of the interview. Participants will be asked to read the consent form (emailed to them prior to the interview). This protects the privacy of the participant by not having to keep a written record of their signed consent form.

### Survey Considerations and OMB Requirements

This will be a research contract therefore OMB approval will be necessary in advance of study activities. OMB will review focus group scripts and survey content. The approval process is expected to take up to 8 months. We plan to begin OMB approval procedures early in 2012.

## 9. Timeline

MSM and Blood Donation	2011				2012												2013		
Study Activities	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M
Administrative																			
Proposal development																			
Full protocol development																			
IRB approval																			
OMB approval																			
Aim 1 - Initial Focus Groups																			
Pilot focus group																			
Focus group planning and study advertising																			
Conduct focus groups																			
Qualitative analysis																			
Reporting of results and manuscript preparation																			
Manuscript submission																			
Aim 2 - Surveys																			
Survey content development																			
Survey planning																			
Survey administration																			
Data cleaning and analysis																			
Reporting of results and manuscript preparation																			
Manuscript submission																			
Aim 3 - Follow-up Qualitative Interviews																			
Telephone interviews																			
Qualitative analysis																			
Reporting of results and manuscript preparation																			



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