

Supporting Statement A for Blood Donation Rules Opinion Study (Blood
DROPS)

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Under [Title 42](#) › [Chapter 6A](#) › [Subchapter III](#) › [Part C](#) › [Subpart 2](#) › § 285b–1 the Director of the National Heart, Lung, and Blood Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities. The proposed study, Blood Donation Rules Opinion Study (Blood DROPS), fits within the NHLB Institute’s research agenda as described here and in the other supporting documents. 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. 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. 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).

Compliance or not with the policy or a modified policy and motivating factors behind those behaviors by MSM and current blood donors are important and as yet unstudied aspects of the larger issue in the U.S. While many scientists and ethicists have expressed opinions in support of or against modification of current MSM policy for blood donation, there is a paucity of data that directly addresses important aspects of this policy debate. The proposed study will build off 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.

A.2 Purpose and Use of the Information Collection

Since 1989, the NHLBI-sponsored Retrovirus Epidemiology Donor Study (REDS) program as well as its extended version, REDS-II, and the current Recipient Epidemiology and Donor Evaluation Study (REDS-III), have conducted epidemiologic, laboratory and survey research in the field of blood safety. In 2006, the REDS-II program initiated an international component, extending the scope of blood safety research to include investigators in Brazil and China. This program was further expanded in 2011 to include South Africa in the REDS-III program. The

current REDS-III program also seeks to further expand the research into health outcomes of blood transfusion recipients in addition to donor-focused. Three research aims and embedded objectives drive this study's protocols to capture motivations and compliance behaviors of MSM and male blood donor respondents.

Aim 1 seeks to assess opinions about and common themes within the MSM population using focus group participants as key informants with respect to blood donation and the current MSM77 policy. An additional aspect of this aim is to use the focus groups to help select proper venues for recruiting MSM into the Aim 2 survey study. In Aim 2, two groups will be surveyed; members of the MSM community who reside in the geographic areas where the REDS-III blood centers collect blood, and male blood donors from the same geographic areas. The goals of the surveys are to obtain estimates of compliance and non-compliance with the current MSM77 policy and to elicit opinions about the current and possible changes to the policy. For Aim 3 qualitative interviews of MSM who have donated out of compliance with the current policy will be conducted to directly assess factors that motivate these individuals to donate. Information from the study will be used to determine the scope of non-compliance with the current policy and the factors that influence both compliance and non-compliance. These data will contribute to policy-making decisions and may provide insights into more effective ways to communicate with potential blood donors in order to improve the safety of the blood supply. Information from all study participants will be kept confidential (see Section A10 for a discussion of protection of confidentiality)

Study Population

Due to budgetary limitations on the study design, a population-based sample of MSM and blood donors from the geographic areas where REDS-III centers are located is not feasible. For the focus group project we will therefore use a purposive sampling frame that will sample participants who are likely to have relevant insights on the topic. The focus group and qualitative interviews will include persons who self-select to participate. Similarly, survey respondents are also likely to self-select in that certain MSM and, potentially, blood donor participants may have particular interest in the subject matter of the survey.

Aim 1 - Focus Groups

Because the population of MSM who have donated or tried to donate is a small and hidden population, we will also broaden the allowed participants to include other HIV-negative MSM to better understand perceptions of the 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.

We will conduct 8 focus groups (2 in each of the four geographic areas where the REDS-III blood centers are located) with 6 to 8 participants per group. Focus groups will be conducted contiguously in order to minimize the amount of travel time conducting field research, i.e. go from San Francisco -> Milwaukee -> Connecticut -> Pittsburgh over an approximately two week period. Investigators at the Center for AIDS Prevention Studies (CAPS) at UCSF will lead the focus group research. The focus groups will elicit 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.

In advance of these focus groups, 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.

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/>.

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 deferrals 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 propose to role play the screening questionnaire and distribute the associated instructions during the focus group so that participants can get a sense of what the donor selection 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. Finally we will ask questions to determine the best venues and times to advertise the MSM survey for Aim 2.

Aim 2 - MSM and Blood Donor Surveys

Aim 2 seeks to assess compliance and non-compliance in the MSM and separately the male blood donor population with the current MSM77 policy. Compliance and non-compliance with the MSM77 policy will be assessed using a survey of the two groups using an instrument that includes common content. 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).

The content is identical except where certain questions are relevant only to the MSM group or the blood donor population.

First, we will conduct a confidential survey of the MSM community that will provide better estimates of compliance and non-compliance with the MSM77 policy. The survey will answer the

following question “Within a population of MSM who are confidentially surveyed, what is the frequency of self-disclosed compliance with the current MSM77 policy?”

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 URL links to complete the survey. 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.

Second, we propose a confidential survey of blood donors to find out how frequently persons with MSM77 behavior are engaging in blood donation. This survey will focus on the question: “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?”

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 the REDS-III blood centers. We plan to recruit survey participants at fixed and mobile donation sites.

Aim 3 - Qualitative Interviews

The purpose of Aim 3 is to assess actual motivations for donating in the population of self-identified MSM who have donated blood in the US after 1977 following their MSM sexual debut.

We plan to use the responses of the web-based surveys from participants in Aim 2 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 geographic areas who report actual blood donation or the intention to donate will be contacted by email and invited to participate in a 60 minute confidential telephone interview. This interview will focus on the research question: “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?” Participants will be asked to complete a qualitative telephone interview that will include content similar to that of the Aim 1 Focus Groups.

A.3 Use of Information Technology and Burden Reduction

The focus group discussions will be conducted in-person using confidential safeguards described in A.10. In the second part of the study, cross-sectional surveys to collect data on compliance and non-compliance using internet-based and telephone interviews will be conducted. For internet-based interview, we will provide secure links for the study that will only be accessible to the persons invited to participate in the study. The previous studies from Sweden and the UK provide the basis for the content that we have developed for the US survey instrument. 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. The potential ability to access groups that are difficult to reach is a critical advantage for the proposed methodology. The proposed internet-survey will allow persons who may not be willing to publically identify as MSM or blood donors to complete the survey in private setting, such as at home.

For the third section of the study of the project, all telephone-based interviews will be conducted by a study research scientist with extensive experience in conducting qualitative interviews with sensitive content. 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 also 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.

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. Video recordings of all focus groups will be encrypted and stored on a password-protected computer. Only study staff analyzing the data will have access to the encrypted videos. Any names or identifiers will be bleeped from the video soundtracks 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.

For internet-based and telephone interviews, measures taken to protect their confidentiality include: University of California San Francisco-approved encryption methods and other methods to physically and electronically secure data, collecting only the minimum amount of information necessary to the conduct of the study, requiring that the researchers will never disclose this information to anyone outside the research team, and destroying the data 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.

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

Motivating factors and compliance or not with the policy or a modified policy by MSM and current blood donors are an important and as yet unstudied aspects of the larger issue of blood donation. The proposed study will collect directly relevant information on the topic of MSM blood donor policy 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. The data collected for this study will provide up-to-date information that does not yet exist and therefore is not a duplication of previous research on this topic. To our knowledge there is no other source of information in the US or other project that could provide the data to be collected by this study.

A.5 Impact on Small Businesses or Other Small Entities

Small businesses or entities are not involved. All respondents are individual persons.

A.6 Consequences of Collecting the Information Less Frequently

Focus groups will be conducted only once with respondents, and questionnaires will be administered only once to respondents. The content of these activities includes respondent demographics, sexual history, history of previous blood donation, and opinions about current and modified MSM blood donation policies. Data collected from each respondent during the focus groups and web-based and telephone interviews is essential to understanding the characteristics of blood donations from the study population and the focus groups and interviews themselves constitute a minimal level of burden on the respondents.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The proposed data collection is consistent with 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-day Federal Register Notice requesting comments was published on pages 10756-10758 in Volume 77 of the Federal Register on January 23, 2012. Six written comments were received, one of which was shared by two signatories. Attachment 9 contains a summary of these public comments. There has been consultation outside of NHLBI to conceptualize and design the proposed study. The final study design was developed, reviewed, and approved by the REDS-III Steering Committee, and the Observational Study Monitoring Board (OSMB) (See Attachment 5 for a complete list of members). The OSMB reviewed the final protocol and provided input and comments.

A.9 Explanation of Any Payment of Gift to Respondents

All participants will be offered electronic gift certificates redeemed online from Amazon.com. 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 the study significant personnel time and avoids some accounting issues. Focus group participants will be offered a \$50 incentive. Internet participants will be offered a \$10 incentive. Telephone survey respondents will be offered a \$50 incentive.

A \$50 incentive is being offered because this amount is what we have used for focus groups of similar (90-minute) length for numerous other federally funded studies among MSM. Typically, these payments for focus groups by UCSF researchers with MSM in major urban areas are \$50 or \$75 for 90 minutes, while commercial studies in San Francisco typically pay higher incentive amounts, sometimes up to \$200. With the pressure of these commercial incentives paying less than \$50 would make subject recruitment difficult. Since our goal is to recruit MSM participants who are similar to blood donors in education and socioeconomic status (SES), both attributes of which are high among this population, a minimum of a \$50 incentive is necessary to ensure sufficient subject recruitment numbers. The web survey completion incentive payment of \$10 is based on our finding that \$25 appeared to encourage persons to try to find ways to attempt to cheat, while a lower amount did not encourage that behavior. In addition, the web survey has a lower respondent

burden than the burden for focus group respondents, and does not require the additional burden of travel expenses required for focus group respondents.

With respect to the qualitative interviews and the provision of an incentive amount of \$50, this amount is appropriate for many of the same reasons we have described for the focus group participants. The participants are expected to have higher education and socioeconomic status. The qualitative interviews will be approximately 1-hour in length, but the respondent will be the only person being interviewed. The amount is appropriate because it emphasizes the importance to the participant of providing information which is impossible to capture in any other way than by direct conversation with MSM who are also or have been blood donors, and have donated by contravening the current MSM77 donor deferral policy. The number of persons who will be willing to speak to us about this topic is not expected to be large and so we need to maximize our chances of getting subjects to participate, providing the proposed incentive amount may help to facilitate participation. Note that for a current study being conducted to identify risk factors in blood donors, we are interviewing blood donors who have tested positive for viral infections and inquiring about personal behaviors. For this study we obtained OMB approval to provide incentive amounts of \$75 owing to the importance of study participants providing details of their sexual behaviors and other behaviors that could place blood recipients at risk for infection from transfusion. We believe the qualitative interview incentive amount, which is \$50 instead of \$75, is appropriate for the nature of the information we are trying to obtain from the participants in this part of the study.

To provide additional context for our proposed \$50 incentive payment for our focus group and qualitative interview participants, we provide here a list of several studies with similar respondent burden and other contextual factors that offered incentives similar to what we propose for our study.

- Investigators for the 2012 Using Tobacco Market Research to Counter-Engineer Young Adult Tobacco Marketing - focus groups. (NCI U01CA154240-01 [PI: Ling, Pamela]) are paying their focus group respondents in San Diego and Oklahoma City \$75 for 30 minute long focus groups and 45 minute individual interviews.
- In 2010 Study Investigators for The Investigating Motivations for Participation in Anal Cancer Prevention Trials (IMPACT) (NCI RC1 CA145117 [PI: Palefsky, Joel]) paid \$50 for 90 minute focus group in 10 US cities including all major metropolitan centers.
- Focus group participants were paid \$50 for 90 minute focus group with MSM in six US cities in 2005 for the Community Prevention Policy & Programs in Risk Settings (COMSET). (NIMH1 R01 MH070311-01A1 [PI: Woods, William]).
- For the 2012 Study Development and implementation of a novel sexual health-oriented mobile health app (application) to assess sexual risk behavior of men who have sex with men (PI: Vallabhaneni, Snigdha) focus group with MSM in San Francisco are being paid \$50. This study is funded through Pilot Study Grant from Center Grant NIMH 5 P30 MH62246-03. Year Conducted: 2012.

- In 2008 the PalmPal Focus Group Study paid \$50 for focus group with HIV test clients in San Francisco. This pilot study of Nicolas Sheon was funded through Center Grant NIMH 5 P30 MH62246-03.
- The study Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance is currently offering incentives of \$75 for infected blood donor interviews and \$35 for uninfected donor interviews. (Study PI: Custer, Brian) HHSN26820047175C. These incentives amounts were approved by OMB. OMB Control #0925-0630, Expiration Date 04/30/2014.
- A study that is currently recruiting focus group participants through Craigslist is offering \$50 for a University of Pittsburgh focus group study. <http://pittsburgh.craigslist.org/vol/2873105322.html>. Currently recruiting.

A.10 Assurance of Confidentiality Provided to Respondents

All respondents will be assured of the actions taken to safeguard their confidentiality of their personal identifiable information and will be informed about the Certification of Confidentiality granted to the REDS-III Study to protect their data from involuntary disclosure (Attachment 7). Details about additional safeguards in place for each component of the Study are described below.

Focus Groups and Privacy of Participant Data

Focus Groups will be video recorded to permit the most accurate coding of valuable data elements presented in each focus group. We recognize the sensitivity of video data and the added risk of loss of privacy over audio data alone when gathering personal identifiable information from our focus group respondents. 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 video analysis computer software 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 stored 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. The lead investigator for the focus group and qualitative interviews portions of the study 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 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. 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 the lead investigator for the focus group and qualitative interviews and the transcriptionist will have access to the encrypted volume. The transcriptionist is experienced in focus group and video transcription. The encrypted volume containing the focus group video will be transmitted to the transcriptionist using a YouSendIt service account. 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 are described at: <http://www.yousendit.com/cms/security>. We will use multiple layers of redundant encryption, email authentication, and passwords for both TrueCrypt and analysis software to secure the video and audio data sent to the transcriptionist.

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. 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.

Web Surveys and Privacy of Participant Data

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

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

Plans to minimize any potential for risk and addressing these three issues are described below, respectively. In addition, a Certificate of Confidentiality, specific to this study 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 to conduct the study, , researchers never disclosing this information to anyone outside the research team, and data being 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.

For all the online surveys (the MSM and Blood Donor surveys), respondents will complete the survey using a web-based survey administration. 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.

Telephone Interviews and Privacy of Participant Data

For telephone interviews conducted for Aim 3 that collect subjects' personal identifiable information, the audio recordings will be in mp3 format and stored in an encrypted volume on a password protected computer. We will use the same data security measures outlined for the transcription and analysis of the video data in Aim 1.

A.11 Justification for Sensitive Questions

Focus Groups

The purpose of this study is to better understand the perceptions of men who have sex with men (MSM) on blood donation deferral policies. We know of no previous qualitative studies on this topic in the US, and therefore little is known about the motivations of MSM who donate blood or how they interpret sexual behavior questions designed to determine donor eligibility. Qualitative interviews with MSM blood donors in the UK were conducted in 2010 and we have adapted our interview topic guide from the topic guide prepared for this UK study.(Grenfell et al., 2011) This is a topic in which attitudes in the US are likely to evolve in light of policy changes in other Anglophone and Western European countries that now permit some MSM to donate blood. In addition, advocacy organizations in the US, such as the GMHC, the American Association of Blood Banks, and key members of Congress have called for an end to permanent MSM blood donor deferral. More data are needed to understand how aware MSM in the REDS-III catchment areas are about donor deferral policy changes that have occurred in other countries, what MSM's awareness of and attitudes towards the FDA policy are, and how these attitudes may influence blood donation behavior in the US.

The reasons underlying why MSM donate blood regardless of the FDA policy are complex, and previous research has only been able to speculate on the possible reasons that male donors fail to disclose same sex behavior. Some of the proposed reasons are (1) denial about risk behaviors based on internalized homophobia; (2) the 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 any transmissible infections will be detected and discarded before being disseminated to blood recipients; (4) a more narrow interpretation of which MSM sexual activities qualify for deferral, such that protective behaviors such as condom use, monogamy, or sex only with partners known to be HIV negative should be considered when determining MSM's eligibility for blood donation; (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 politically acceptable from the donor's perspective.

Focus groups and individual interviews are two complementary methods of qualitative research typically used to explore complex issues about which little is known. (Arnold & Lane, 2011) Focus groups are particularly useful for identifying a range of perspectives and social norms on controversial topics.(Crossley, 2003) Individual interviews complement focus groups by illuminating individual experience of an issue in order to understand its significance in the context of other life experiences. (Kvale & Brinkman, 2008) While focus groups are structured to elicit participant stances through naturalistic observation of how people debate controversial issues,

individual interviews are designed to elicit personal narratives. The more public nature of focus groups militates against sharing of personal stories, while the intimacy of confidential individual interviews, particularly over the telephone, encourages in-depth exploration and disclosure of personal experiences, attitudes and perspectives about which participants may not have previously thought about.

It is with these complementary approaches in mind that we have designed the focus group and telephone interview topic guides. Participants in focus groups and individual interviews will be asked about their perspectives on policies designed to exclude MSM, but only the telephone interview asks participants to describe their personal experiences as blood donors and how these relate to their sexual orientation. As noted in A.10, personal identifiable information will be collected from participants in these three activities, and the safeguards to ensure confidentiality are discussed in Section A.10. The telephone interviews will be conducted with survey participants report blood donation and MSM behavior since 1977 and agree to participate in the follow-up interview. Although focus group participants must report MSM behavior to be eligible, blood donation is not an eligibility requirement for focus group participation. As a result, focus group participants will be asked to speculate on the motivations of MSM blood donors rather than describe their own blood donation experiences.

Focus Group Topic Guide

1. 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.
2. Review of eligibility questions via role play.
 - How should sexual contact between men be defined?, e.g. in terms of condom use, number of partners?
 - How should sexual behavior questions be asked?, e.g. by person or by computer?
3. Perceptions of MSM's motivations for non-compliance with the rules and for donating blood.
4. 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?
5. Suggestions of venues for recruitment of local MSM for the survey?
6. How has this discussion changed your views on blood donation?

References

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- Grenfell, P., Nutland, W., McManus, S., Datta, J., Soldan, K., & Wellings, K. (2011). Views and experiences of men who have sex with men on the ban on blood donation: a cross sectional

survey with qualitative interviews. *BMJ*, 343(sep07 2), d5604–d5604. doi:10.1136/bmj.d5604
Kvale, S., & Brinkman, S. (2008). *InterViews: Learning the Craft of Qualitative Research Interviewing*. Sage Publications.

Self-completed Surveys

The aims of the survey of the MSM population and the male blood donor population are to assess compliance and non-compliance with the current FDA blood donation policy in the US that prevents men who disclose having had any male-male sex since 1977 from donating blood. Persons who are willing to donate blood are asked many sensitive questions regarding behaviors that have been associated with higher risk of infections that could be transmitted by transfusion. These blood donor questions include questions about sexual behaviors. The survey questions that we plan to use in this study will ask similar questions of the participants outside of the setting of blood donation. In addition to assessing the prevalence of non-compliance within the MSM community and for male blood donors, we will ask all respondents to provide their opinions about the current policy and potential modifications to the policy.

The reasons underlying why MSM donate blood regardless of the FDA policy are undoubtedly complex and previous research has only been able to speculate on the possible reasons that donors fail to disclose same sex behavior. Some of the proposed reasons are (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.

Justifications for question content are based on groups of questions with similar content. There is no other way to determine the prevalence of compliance and non-compliance with the FDA policy and the underlying factors that may influence compliance other than to ask males who self-identify as MSM and to ask male blood donors the same questions. Direct questioning via a confidential survey is the only method by which disclosure of non-compliance and related motivations can be assessed.

Self-completed Survey Topic Content

Screener Questions are intended to delineate the population under study.

Questions 1-9, and 12 will be asked of all respondents on the MSM survey and the male blood donor survey. Although we are asking about the participants age in question 3, we asking for similar information in question 12 so that we can more precisely define the age of participants and also to be able to ensure that only persons 18 years or older complete the survey. In addition, question 12 will only be asked if the potential participants have answered all of the preceding eligibility screener questions.

These questions cover basic demographic and geographic information that are necessary to ensure respondents are eligible to participate in the study.

Screener Questions 10 and 11 will be asked of MSM survey respondents only.

These questions are necessary in order to establish that the respondents are MSM who do not know themselves to be infected with the viral infections of most concern in blood safety.

Survey Questions

These questions will allow us to determine whether respondents, regardless of how they define their sexual orientation, have had sexual contact with females or other males in their life and how recently the last contact occurred. Questions 13, 14, 17, 18, 21, 22, and 27 are modified versions of questions used in a similar study conducted in the United Kingdom (UK). (Source: London School of Health and Tropical Medicine (LSHTM) Survey – FINAL Questionnaire H938A – JN: 45108303 – 07 Apr 2009). The primary modifications are that the definition of sex between the UK study and the planned US study are slightly different and the US study will assess specific time periods in which male-male sexual contact may have occurred. We have added content on male-female sex (Questions 15 and 16) for two reasons. First, we want to assess in a parallel manner the number of sexual partners that heterosexual, bisexual, and homosexual respondents may have had during the same time periods. Second, this information is important because of the concerns that both blood recipient advocacy groups and LGB T advocacy groups have stated out of the need to better understand the broader sexual exposure patterns of blood donors and non-blood donors. These data are necessary to collect in order to more fully inform the current understanding of sexual exposures in the blood donor population. The modifications are necessary to reflect the relevant definition of sex used in the US blood banking context and to reflect the relevant time periods with respect to the blood donation policy in the US. These questions will provide a baseline understanding of respondents’ sexual histories and will allow us to interpret opinions and perspectives disclosed in subsequent questions based on sexual history. Skip patterns are built into the questionnaire so if respondents report “no” or “never” to initial “ever in your lifetime” to male-male or male-female sex questions, more detailed specific questions will not be asked.

Questions 21, 22, 23, 24, 25, and 26 will be asked of all respondents on the MSM survey and the male blood donor survey.

These questions will be used to determine whether respondents are in sexually monogamous relationships. A potentially modified blood donation policy could be based on allowing MSM in monogamous relationships, who are otherwise eligible to donate, to give blood. Gay advocacy groups such as Gay Mens Health Crisis (GMHC) have suggested that this type of policy should be considered. The questionnaire content will provide information on this topic specific to the context of blood donation. Similar relationship status questions are asked of all respondents including men who have never had male-male sex. Skip patterns are built into the questionnaire and so if respondents report “no” to “married or long-term relationship” follow-up questions will not be asked.

Questions 28, 29, 30, and 31 will be asked of respondents on the MSM survey.

These questions are modified to reflect the US policy but are directly based on the study conducted in the UK (LSHTM Survey – FINAL Questionnaire H938A – JN: 45108303 – 07 Apr 2009). The questions will assess the prevalence of non-compliance with the current FDA policy on blood donation by MSM and factors that may contribute to compliance and non-compliance with the

existing policy. Skip patterns are built into the questionnaire and so if respondents report “no” or “never” to initial “ever” questions more detailed specific questions will not be asked.

Questions 32, 33, and 34 will be asked of all respondents on the MSM survey and the male blood donor survey.

These questions have been used in previous studies authorized by OMB (OMB Control #0925-0630, Expiration Date 04/30/2014). The questions include content that examines blood donation history and motivations for donating including motivations that are not altruistic and therefore are only likely to be disclosed by confidential survey.

Questions 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, and 46 will be asked of all respondents on the MSM survey and the male blood donor survey.

New. These questions will be asked to assess respondents’ understanding of the current FDA policies including male-male sex and then will seek to assess opinions on the degree of agreement with factors that may influence donation behavior and with potential modified MSM policies. Question 34 includes a brief assessment of respondent knowledge of behaviors or factors that may make individuals eligible or ineligible to donate. Each of the factors listed may be a true or untrue basis for excluding persons from blood donation. The remaining questions assess opinions.

Questions 46 and 47 will be asked of respondents on the MSM survey.

New. These questions will be asked to assess whether compliance with a male-male sex blood donation policy would change in the MSM population if the current policy was modified.

Questions 48, 49, 50, 51, 52, 53, and 54 will be asked of all respondents on the MSM survey and the male blood donor survey.

These questions are modified to reflect the USA policy but are directly based on the study conducted in the UK (LSHTM Survey – FINAL Questionnaire H938A – JN: 45108303 – 07 Apr 2009). The questions will assess how opinions about blood donation and blood donation policy influence blood donation behavior and the potential impact on the MSM population and male blood donors if the current male-male sex policy was changed.

Question 55 will be asked of all respondents on the MSM and the male blood donor survey.

This question is necessary in order to be able to provide the participation incentive to all study participants who complete the survey. This question is optional and participants may leave it blank. However if the respondent does not supply this information we will not be able to provide the \$10 electronic certificate participation incentive.

Telephone Survey

The telephone interview topics discussed will be similar to the focus groups in Aim 1. This interview will also include questions about specific blood donation experiences, motivations for donation, and questions about sexual orientation and blood donation found in the self-completed web-based survey topic guide. The interviews will be conducted by an investigator who has extensive experience interviewing MSM about their experiences and creating a safe and secure

space for participants to articulate sensitive information. Telephone interviews offer the advantage of being conducted in a private place (e.g. the participant's home) at a mutually convenient time. And, individual participants are able to provide a longer narrative of their experiences, and are more likely to discuss sensitive issues one on one than in the focus group setting.

Individual Telephone Interview Topic Guide

The individual telephone interviews will cover the same six topics provided in the Focus Group Topic Guide above, plus the following topics related to past experiences donating blood, and questions about how the interviewee's sexual orientation relates to their blood donation motivations.

7. Past Blood Donation Experiences.

- How long have you been donating blood? How often?
- Describe the most recent time you gave blood, the information you were given by staff, the administration of the screening questions, how you responded on paper and when asked by staff about your deferral risks, how you were treated by staff, if you will go back again?
- Describe the first time you donated blood, when it was, what made you decide to donate.
- How have your reasons for donating blood changed over time? What aspects of blood donation would make you more or less likely to donate again?
- Have you ever tried to donate blood but were refused?

8. Sexual Orientation and Blood Donation

- How do you usually describe your (sexual) orientation?
- For you, is sexual orientation a matter of who you're attracted to? Who you have sex with? Current relationship? Past relationships? How you relate to people? Where you meet people?
- Have you always identified as ____? How has this changed over time?
- How has your sexual identification/orientation affected your views on blood donation?
- How important to you are the rules around MSM's eligibility for blood donation?

A.12 Estimates of Hours Burden Including Annualized Hourly Costs

The burden hours for each of the study Aims was estimated based on experience. The Aim 1 focus groups will be conducted for fixed lengths of time – 90-minutes. This has been shown to be an optimal time for participants. Groups that are shorter than 90 minutes do not elicit the breadth of information a longer session does, but sessions that last longer than 90-minutes result in lapses in attention. The Aim 2 screeners and web interview estimates are based on the investigator experience using similar numbers of questions of the same general type in web-based research. The screener covers a total of 15 separate items requiring responses from potential participants. Most of the items are demographic characteristic questions which

take very little time to complete. The entire screener from the moment of logging on to the website hosting the screener to the completion should not take more than 10 minutes for any respondent. The Aim 2.1 and 2.2 surveys contain up to 56 individual items requiring response. The actual number of items that will require responses will vary by individual completing the interview because there are built-in skip patterns in each interview. Based on previous experience we believe it will take on average 20 minutes for each respondent to complete the Aim 2.1 or 2.2 interviews. For Aim 3 the qualitative interviews, we are allowing and planning for up to an hour long conversation with each participant. The reason an hour long interview is planned is that the subject matter covered during the interview is sensitive. It will be necessary for the interviewer to develop a report with the respondent before engaging on the topic of why individuals are donating and not disclosing deferrable risks. The reasons or justifications that respondents provide may be complex and multi-faceted and so hour long interviews are expected.

A.12.1 – ANNUALIZED BURDEN HOURS TO RESPONDENTS

Study Aims	Estimated Annual Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Aim 1 – Focus Groups	64	1	1.5 hours	96
Aim 2.1 – Web screener	2,000	1	.10 hours	200
Aim 2.1 – Web interview	1,600	1	0.33 hours	528
Aim 2.2 – Web interview	3,200	1	0.33 hours	1056
Aim 3- Telephone Survey	20*	1	1 hour	20
Total				1,900

*Aim 3 respondents are a subset of the respondents included in Aim 2

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost – all respondents
Aim 1 – Focus Groups	64	1	1.5 hours	8.00	\$768
Aim 2.1 – Web screener	2,000	1	.10 hours	8.00	\$1,600.
Aim 2.1 –	1,600	1	0.33 hours	8.00	\$4,224

Web interview					
Aim 2.2 – Web interview	3,200	1	0.33 hours	8.00	\$8,448
Aim 3 – Telephone Survey	20*	1	1 hour	8.00	\$160
Total					\$15,200

*Aim 3 respondents are a subset of the respondents included in Aim 2

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

There are no capital or start-up costs, and no maintenance or service cost components to report.

A.14 Annualized Cost to the Federal Government

The annual total cost to the Federal Government for the proposed study is estimated to be approximately \$380,000. The costs of planned activities for this study are provided in table 14-1 according to the phase of the project. The total costs in each part of the study includes personnel time (salaries) for the investigators and research staff, and Activity specific items such as provision of the incentive amounts for participants during the Participant Enrollment and Data Collection phase of the study.

A.14 - 1 Annualized Costs	
Activity	Total Cost
Initiate Study Recruitment Activities	91,000
Participant Enrollment and Data Collection	185,900
Data Management and Analysis	103,100

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A16 Plans for Tabulation and Publication and Project Time Schedule

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Initiate Study Recruitment Activities	Immediately following OMB approval 2013
Participant Enrollment and Data Collection	Two months from OMB approval.
Data Management and Analysis	Ongoing through 2013

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed in the upper-right hand corner of the questionnaire.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement of OMB Form 83-I.