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

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B.1 Respondent Universe and Sampling Methods

Aim 1 Focus Groups

The target population for the focus group research is the population of men who have a history of male-male sexual contact and live in the counties where the REDS-III blood centers collect blood. The size of this population is unknown because of the absence of census data on MSM. There is no method to identify potential participants except if they complete the web-based study recruitment form. In this way the participants will not be representative of the larger MSM population in the REDS-III communities. The participants will represent a self-selected convenience sample of men who have a history of male-male sex and who are interested in the topics of blood donation and blood donation policy. The analytic unit is the individual person.

Flyers will be posted at local community organizations, such as gay and lesbian community centers, gyms, cafes, and support groups in each of the four cities. Advertisements will be posted 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.] A pilot focus group of up to 8 participants will be conducted in San Francisco. We will conduct two focus groups in each of four areas where the REDS-III blood centers are located. Each group will have 6-8 participants for a total of up to 64 participants in Aim 1.

Statistical analysis methods will not be used for Aim 1. Analysis will be conducted to determine whether certain themes or beliefs are widely shared among the group of participants, or idiosyncratic among certain participants. The focus groups will enable us to identify particularly rich descriptions that will be useful for a more in-depth understanding of the potential motivations for blood donation among this population. This information will provide a broad context for understanding opinions and perspectives on MSM behavior and blood donation policy.

Aim 2.1 Survey of MSM

The target population for the MSM survey is the population of men who have a history of male-male sexual contact and live in the counties where the REDS-III blood centers collect blood. The size of this population is unknown because of the absence of census data on MSM. The survey population will be those men who self-select to complete the online survey.

The study is intended to estimate the frequency of compliance and non-compliance with the current MSM blood donor policy in the USA. As such, a specific hypothesis is not being tested. Assuming a MSM population of 115,700 in the REDS-III primary cities (San Francisco, Pittsburgh, Milwaukee, and New Haven) but not including the broader MSM population in adjacent counties, a MSM survey sample of 1600 respondents (400 per REDS-III location) will be needed to estimate a previous donation history of 19% (as suggested by the Swedish Study) with a 95%CI of 17 – 21% for the overall sample and 15 – 23% for each location. With these sample sizes, even if the actual prevalence of non-compliance is as low as 11% or as high as 29% (as suggested by the UK study), precision will be unaffected, i.e., confidence interval

widths would be about 5 percentage points (plus or minus 2.5%) for the overall estimate and about 10 percentage points (plus or minus 5%) within location.

Aim 2.2 Male Blood Donor Survey

The target population for the male blood donor survey is the population of men who have donated blood at one of the four REDS-III blood centers. The size of the male blood donor population in a one-year period for the four REDS-III centers is approximately 165,000 persons. The sample size for the survey is approximately 2% of the male blood donors at each center. Among the donor population, the survey population will be those men who self-select to complete the online survey.

Blood Center	Male Blood Donor Population (individual donors per year)	Sample Size
American Red Cross, Connecticut	40,000	800
Blood Centers of the Pacific, San Francisco, CA	37,000	800
Blood Center of Wisconsin, Milwaukee, WI	47,000	800
Institute for Transfusion Medicine, Pittsburgh, PA	41,000	800
All Centers	165,000	3200

A sample of 3200 male blood donors (800 per location) will be sufficient to determine a prevalence of undisclosed male-male sex in donors of 1.2% with a 95% CI of 0.85 – 1.64% (0.57 – 2.22% within location) if the prevalence of non-compliance is similar to data reported in the countries of Sweden and the United Kingdom.

Aim 3 Qualitative Interviews (Telephone)

For Aim 3 the target population is composed of participants of Aim 2 surveys recruited for the qualitative interview based on their "yes" responses to the question about same-gender sex and current and past blood donation. They are those individuals who chose to disclose non-compliance with the current MSM blood donation policy, provide contact information, and consent to be confidentially interviewed by telephone. This group of men is a convenience sample and cannot be considered representative of any other group. This group is a purposive sample of the eligible survey participants. However, the responses they give to the topics on the interview guide are critical for obtaining a broader understanding of opinion and perspectives of the population of MSM who donate blood.

There is no way to identify a representative sample of this subpopulation. It will not be easy to identify many study participants who are eligible and willing to participate in the qualitative interviews. For that reason it is anticipated that up to 20 interviews may be conducted in Aim 3. Statistical analysis methods will not be used for Aim 3. Analysis will be conducted to determine whether certain themes or beliefs are widely shared among those men who consent to be interviewed by telephone.

B.2 Procedures for the Collection of Information

For all Aims except Aim 2.2, because we do not have a complete understanding of the sampling frame for the other Aims, the participants will be a convenience rather than representative sample. For Aim 2.2, the blood donor survey, we have an estimate of the population. However, those donors who choose to complete the survey may not be representative of the blood donor population because of the sexual nature of the survey content.

All of the proposed focus group, survey and interview activities will be conducted during discrete time periods. For Aim 1, focus groups will be conducted during a two-week period. For Aim 2, surveys of MSM and surveys of blood donors will be conducted during a 3-month interval currently planned for 2013. For Aim 3, qualitative interviews will be conducted over a one-month period.

For Aim 2.1, in order to achieve study enrollment and maximize exposure of the MSM population to the study, the study will be advertised in the local communities. 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 (places and times where the populations of interest congregate) that will direct potential participants to the Internet survey. Venues will be selected for maximum impact on the general population of MSM.

For Aim 2.2, we will invite male blood donors 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 REDS-III blood centers. We will recruit survey participants at fixed and mobile donation sites by handing out cards that will provide the URL for accessing the survey.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The requirement of Internet access in order to participate in the study tends to select for higher socioeconomic status individuals. However, research has shown that such individuals are more likely to be potential blood donors 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.

With respect to monitoring, it will not be possible to monitor for non-response, but the researchers will be able to collect real time information on survey completion and how frequently respondents begin but terminate the survey before completion. This allows for tracking recruitment efforts and participation, 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. The information systems and software used to conduct the survey will not allow for the survey to be completed multiple times from the same computer IP address.

Geographic specificity of the MSM and blood donor surveys: This is a potential 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 organizations in the specific communities, 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. To maximize the specificity of the geographic area the first three digits of each participant's zip code of residence will be collected. Only surveys that include this information will be included in the analytical dataset and only surveys from zip code areas captured in the same counties where each of the REDS-III centers collects blood will be allowed.

B.4 Test of Procedures or Methods to be Undertaken

We will conduct a pilot focus group to assess if the focus group content, guide, and facilitator are achieving the objective of providing insights to the factors that may influence the MSM population to or not to donate blood.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Members of the research team are qualitative research experts, epidemiologists and biostatisticians. We have consulted with the REDS-III blood centers researchers as well as the REDS-III Coordinating Center staff for protocol development, study monitoring, and data management. Data analysis will be performed by the analytic staff at the UCSF Center for AIDS Prevention Studies that includes epidemiologists and biostatisticians. Oversight will be provided by the REDS-III Oversight Committee (see Attachment 6 for a complete list of Oversight Committee members). The REDS-III OSMB (Attachment 5) will monitor the study.