

**OMB Justification for Change**

Project Title: Hemophilia and AIDS/HIV Network for the Dissemination of Information (HANDI) Evaluation Support

Project Number: OMB 0920-0858

Estimates of Annualized Burden Hours and Costs: There is no change to the estimated annualized burden hours and cost estimates since the design has not changed with the exception of conducting the focus groups by telephone instead of in-person. The number of groups planned to be held and number of participants per groups has not changed. It is estimated that 120 respondents will have to be screened in order to recruit 108 focus group participants. Each screening will take approximately 12 minutes. The estimated response burden for the screening process is 24 hours. The focus groups will have an average of nine participants each. Twelve focus groups will be conducted, with a total of 108 participants. Each focus group will take 90 minutes, for a total burden of 162 hours. The informed consent will take approximately 6 minutes to complete, for a total burden of 11 hours.

**A. Estimated Annualized Burden Hours**

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Participant Screener and Recruitment Script	120	1	12/60	24
Young adults aged 16–19 living with hemophilia					
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Moderator’s Guide	108 (12 groups x 9 participants per group)	1	1.5	162
Young adults aged 16–19 living with hemophilia					
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Informed Consent	108 (12 groups x 9 participants per group)	1	6/60	11
Young adults aged 16–19 living with hemophilia					
<b>TOTAL</b>		<b>336</b>	<b>—</b>	<b>—</b>	<b>197</b>

**B. Estimated Annualized Burden Costs**

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate (\$)	Total Respondent Costs (\$)
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Participant Screener and Recruitment Script	120	1	12/60	24	20.32	488
Young adults aged 16–19 living with hemophilia							
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Moderator’s Guide	108 (12 groups x 9 participants per group)	1	1.5	162	20.32	3,292
Young adults aged 16–19 living with hemophilia							
Parents of adolescents (aged 5–12) and parents of teens/young adults (aged 16–19) living with hemophilia	Informed Consent	108 (12 groups x 9 participants per group)	1	6/60	11	20.32	224
Young adults aged 16–19 living with hemophilia							
<b>TOTAL</b>		<b>336</b>		<b>—</b>	<b>197</b>	<b>—</b>	<b>\$4,004</b>

The hourly wage cost is based on the U.S. Department of Labor’s “May 2008 National Occupational Employment and Wage Estimates,” which lists the mean hourly wage for all occupations as \$20.32. See [http://www.bls.gov/oes/current/oes\\_nat.htm#b00-0000](http://www.bls.gov/oes/current/oes_nat.htm#b00-0000)

Methodology: The originally approved methodology will remain the same with the exception of conducting the focus groups by telephone (using a toll-free number) instead of conducting the groups in-person. Additionally, participants will be recruited from throughout the U.S, instead of the four cities originally targeted (Atlanta, GA; Detroit, MI; Philadelphia, PA; San Francisco, CA). Each of the 12 focus groups will still have an average of 9 participants, for an approximate total of 108 human subjects. The two target audiences remain the same:

- (1) Young adults aged 16–19 living with hemophilia
- (2) Parents of adolescents aged 5–12 and parents of teens/young adults aged 16–19 living with hemophilia.

Groups will still be led by a professionally trained focus group moderator and last approximately 90 minutes as originally proposed. An Informed Consent Form will still be obtained from all of the participants before the discussion. The recruitment firm will ask if the person would like to be mailed a consent form that would have an addressed, postage-paid return envelope for the participant to mail back the signed consent form. They will also be given the option to receive a PDF file that they could sign and send back via facsimile.

Changing the methodology from face-to-face focus groups to telephone focus groups does not change the inherent limitations associated with the study design such that qualitative research (focus groups) has limitations and results are less generalizable. However, these groups still yield valuable information to guide and inform future efforts.

Recruitment:

The National Hemophilia Foundation (NHF) will send an e-mail blast to the approximately 6,000 people affected by bleeding disorders listed in their organization's database with information about the telephone groups and the toll-free number to call to get more information and/or find out if they qualify to participate in one of the groups. Upon reading the brief email, interested individuals can choose to call the 1-800 number provided or not. Any action taken by individuals at this point is completely voluntary.

In addition, NHF will send revised recruitment fliers and banners to each Hemophilia Treatment Center (HTC) and Chapter head to post on their web site and/or Facebook page. Each HTC and chapter will assist in recruiting efforts by posting recruitment flyers where potential participants are likely to be present. The revised recruitment fliers will reflect the change from in-person focus groups to telephone groups and provide the new dates and times as well as a toll-free number prospective participants will be instructed to call if they are interested in participating. Approximately, one week after contact with the HTCs and Chapters, ICF will do a follow-up call to ensure receipt of the recruitment materials and to encourage their cooperation with the recruitment effort.

All calls to the toll-free number will be answered directly by a recruiter at Market Ease, a recruitment firm based in Chicago. All callers will be screened using the OMB-approved screening instrument and eligible callers will be assigned to focus groups on a first-come, first-served basis until all groups are

filled. Given that hemophilia affects primarily males, the adolescent groups will naturally be mostly filled with male participants. However, for the parent focus groups, the Recruiting Firm, will attempt to recruit a mix of moms and dads. Eligible individuals who may not be selected for a group will be notified and asked if they may be kept on a list in case of cancellations.

During the screening process, the recruitment firm will collect data on participants' name, address, race/ethnicity, age, education level, and whether they have hemophilia. This information will be used by the recruiting firm to schedule participants for the groups, mail out a confirmation letter verifying the person's participation providing the exact date, time and instructions for dialing into the telephone focus group, and to mail the \$50 incentive to participants after the groups, as well as an iTunes gift card valued at \$15 to the first 10 adolescent participants to qualify. The recruitment firm will pass on participant demographic data to ICF Macro and the CDC after removing identifying information such as their last name, phone number and address. CDC, NHF, and ICF Macro will not have access to the subjects' names and addresses.

Instruments: The moderator guides for the focus groups will contain only minor changes. For example, any references to posting ground rules or discussion points on a flip chart will be eliminated. Also, the group exercise will be modified so that participants can conduct the exercise independently rather than as part of a group. Lastly, the false close will be adapted so that observers listening on the line can email additional clarifying questions to the moderator prior to the close of the groups if they have any.

The recruitment screeners will be modified to change references to focus groups to telephone focus groups and to eliminate the references to videotaping the sessions since only audiotaping will be possible. The location column in the focus group schedule table will also be removed and the reference to providing light snacks/refreshments will also be removed.

The informed consent forms will also be revised as will the recruitment flyers.

Reason for Change: Attempts to recruit sufficient numbers of people from the 4 originally selected cities to participate in the in-person focus groups were unsuccessful despite extending recruitment over a four-month time period. By casting a wider net and recruiting nationwide we will be able to reach more potential participants. Further, we believe that by changing to a telephone focus group methodology we can boost recruitment rates by eliminating the barrier of participants needing to travel to a focus group facility, which for some may require a 2 hour drive and precipitate the need to make and pay for childcare arrangements.

Incentives: We have reduced the amount of the incentive. We are requesting approval of a \$50.00 incentive as the barriers we've encountered thus far with recruitment provide yet further evidence of just how very difficult this population is to reach. In addition, the first 10 adolescent participants to qualify will receive an iTunes gift card valued at \$15. We acknowledge that holding the focus groups by phone is a considerable decrease in participant burden and might result in increased response rates due to the elimination of the need to travel to a facility.

People with hemophilia comprise a small group who regularly receive requests to participate in research projects from pharmaceutical companies who are able to provide far greater monetary incentives than we are. So, although we have eliminated one potential barrier to participation (e.g., travel to a facility), we are still facing other recruitment barriers that are more difficult to overcome.

As we are also seeking people aged 16-19 living with hemophilia, it is extremely challenging to recruit them due to their already overscheduled lives. This age group has many extracurricular activities (sports, clubs, martial arts, etc.), social engagements, and family and civic commitments that could preclude them from taking part in this important research project. We need to offer an incentive high enough that would encourage people to take part in these important focus groups.