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

Gretchen Simmons
Health Education Specialist/Technical Monitor
Telephone: 404-498-6734
Fax: 404-498-6799
E-mail: gmsimmons@cdc.gov
March 25, 2010

Supporting Statement Part A. Justification

Office of Management and Budget (OMB) Package
Hemophilia and AIDS/HIV Network for the Dissemination of Information (HANDI) Evaluation Support
CDC Contract Number #200-2007-20003

Supporting Statement Part A. Justification

Section A.1. Circumstances of Information Collection

Background

This Information Collection Request is submitted under the classification "new" request. The length of data collection requested for OMB-PRA approval is one year.

In September 2009, the Centers for Disease Control and Prevention's (CDC) Division of Blood Disorders, located within the National Center on Birth Defects and Developmental Disabilities (NCBDDD), initiated the National Hemophilia Foundation's (NHF) Hemophilia and AIDS/HIV Network for the Dissemination of Information (HANDI) project—as authorized by the Public Health Service Act, Title 42 United States Code—The Public Health and Welfare, Chapter 6A—Public Health Service, Subchapter II—General Powers and Duties, Part A—Research and Investigations (see *Public Health Service Act, 42 USC Sec. 241* Attachment 1A, and the *Child Health Service Act* Attachment 1B).

The Division of Blood Disorders, located within NCBDDD, implements health promotion and wellness programs designed to prevent secondary conditions in people with bleeding and clotting disorders. These programs are carried out in partnership with community-based organizations on the national and local levels. The division's largest and longest standing cooperative agreement is held by the NHF. NHF, founded in 1948, has a long history of service through education, advocacy, and research for people and families with hemophilia and other bleeding disorders.

HANDI is NHF's resource center that provides information, materials, and support to people with bleeding and clotting disorders. Over the past 17 years, HANDI's resource collection has grown to meet the changing needs of the community. HANDI processes thousands of requests for information from a wide variety of individuals and organizations, including NHF chapters, medical professionals, consumers and their families, and teachers and students conducting research.

The type of information requested reflects a diversity of needs; topics include home care, orthopedics, physical therapy, rare factor deficiencies, psychosocial issues, blood safety, women's health, and financial and insurance reimbursement issues. HANDI's current resource library collection contains nearly 13,000 items.

While many HANDI materials that focus on parents and family members of newly diagnosed children seem to be available, considerably less attention has been given to developing materials for young children and adolescents, particularly materials that address transition issues. Many types of transitions occur for the person with a bleeding disorder. These include accepting the bleeding disorder, administering self-care, progressing through school, planning for a vocation or career, moving to an adult center, starting a family, experiencing middle age, and retiring. Transition occurs throughout life for all people, but for those with chronic illness, it takes on additional significance owing to the nature of their condition.

These gaps need to be filled by developing information that can help parents of young children, adolescents, and young adults best manage their health during these transition periods. Conducting in-person focus groups is the best way to ensure that these new health promotional materials are useful and on target. The information gleaned from these

groups will help determine the content and types of messages needed by these audience segments.

Privacy Impact Assessment

(i) Overview of the Data Collection System

CDC will collect qualitative data through in-person focus groups. The following information will be collected:

- Information needs related to transition issues of young children (aged 5–12) and adolescents (aged 16–19) living with hemophilia.
- Information needs related to transition issues for parents of young children and adolescents living with hemophilia.
- How these target audiences prefer to receive health messages and health information.
- When these target audiences think it is important to begin receiving information on transition issues.

A total of 12 focus groups with the target audiences are scheduled for January/February 2011 in four cities: Atlanta, GA; Detroit, MI; Philadelphia, PA; and San Francisco, CA. These in-person focus groups will include (1) parents of young children (aged 5–12) or parents of young adults (aged 16–19) living with hemophilia and (2) adolescents (aged 16–19) living with hemophilia. The focus groups will be conducted with eight to nine participants in each and will last no more than 90 minutes. The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. More detailed information is provided below.

(ii) Items of Information to Be Collected

CDC/NCBDDD is requesting OMB-PRA approval for 9 new instruments to be used for formative research to gather information in order to develop health promotional materials for the NHF's HANDI. The instruments include:

1. *Participant Screener and Recruitment Script for Young Adults Aged 16–17* (Attachment 3)
2. *Participant Screener and Recruitment Script for Young Adults Aged 18–19* (Attachment 4)
3. *Participant Screener and Recruitment Script for Parents of Children Aged 5–12 or Parents of Teens/Young Adults Aged 16–19 Living With Hemophilia* (Attachment 5)
4. *Moderator's Guide: HANDI Focus Groups—Young Adults Aged 16–19 With Hemophilia* (Attachment 6)
5. *Moderator's Guide: HANDI Focus Groups—Parents of Children Aged 5–12 or Parents of Teens/Young Adults Aged 16–19 Living With Hemophilia* (Attachment 7)
6. *Informed Consent Form for Parents and for Youth* (Attachments 8a and 8b)
7. *Informed Consent Form for Youth* 18–19 (Attachment 9)

(iii) This data collection system will not host a website.

Overview of the Data Collection System

As described above, CDC will collect qualitative data through in-person focus groups. The data will be collected via ths use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. All information gathered will be stored and maintained for the length of the project. Each recruiter, moderator, observer, notetaker, and transcriptionist will be asked to sign a *Privacy Protection Agreement* as shown in the following two attachments:

1. *Privacy Protection Agreement for Focus Group Recruiters, Moderators, Note Takers, and Observers* (Attachment 10)
2. *Privacy Protection Agreement for Transcribers* (Attachment 11)

Data Collection Partners: Upon completion of each focus group, the audiotapes will be sent to Focus Forward, a professional transcription company that will produce both electronic and written versions of the transcripts. When the electronic versions of the transcripts are returned to ICF Macro, the moderator will edit each transcript to remove all references to each participant's identity beyond his or her first name.

Length of Time of Data Maintenance: After completion of the project, all tapes and transcripts will be destroyed.

ICF Macro will work with CDC and NHF, through its chapter network, to identify and recruit focus group participants. The following NHF chapters will assist with the recruitment of focus group participants:

Atlanta:	Hemophilia of Georgia 8800 Roswell Road, Suite 170, Atlanta, GA 30350 Telephone: 770–518–8272; Fax: 770–518–3310
Detroit:	Hemophilia Foundation of Michigan 1921 West Michigan Avenue, Ypsilanti, MI 48197 Telephone: 734–544–0015 or 800–482–3041; Fax: 734–544–0095
Philadelphia:	Delaware Valley Chapter of the National Hemophilia Foundation_ 222 South Easton Road, Suite 122, Glenside, PA 19038 Telephone: 215–885–6500; Fax: 215–885–6074
	Western Pennsylvania Chapter of the National Hemophilia Foundation 20411 Route 19, Unit 14, Cranberry Township, PA 16066 Telephone: 724–741–6160; Fax: 724–741–6167
San Francisco:	Hemophilia Foundation of Northern California 6400 Hollis Street, Suite 6, Emeryville, CA 94608 Telephone: 510–658–3324; Fax: 510–658–6111

Each chapter will assist in recruiting efforts by posting recruitment flyers where potential participants are likely to be present. The flyer contains a toll-free telephone number that interested individuals can call to receive more information and enroll in a focus group.

Focus groups will take place at a professional focus group facility in each city. The following is a list of the market research firms that will host the focus groups:

Atlanta:	Delve Market Research: 2970 Clairmont Road NE, Suite 500, Atlanta, GA 30329 Telephone: 404–321–0468 or 800–227–2974; Fax: 404–636–3276
Detroit:	Opinion Search: 21800 Melrose, Suite 12, Southfield, MI 48075 Telephone: 248–358–9922; Fax: 248–358–9914
Philadelphia:	Delve Market Research: Two Greenwood Square, Suite 130, 3331 Street Road, Bensalem, PA 19020
	Telephone: 215–639–8035 or 800–752–2027; Fax: 215–639–8224
San Francisco:	Schlesinger & Associates: 150 California Street, Suite 800, San Francisco, CA 94111 Telephone: 415–781–2600; Fax: 415–781–2601

Items of Information to be collected

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 and provide the exact date, time and location of the focus group. The recruitment firm in each city 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.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This research will not involve Web-based data collection methods and will not refer respondents to a website.

Section A.2. Purpose and Use of Information

The CDC's Division of Blood Disorders, in conjunction with NHF, will conduct focus groups to gather information that will be used to design educational materials and health promotion programs for young children (aged 5–12 years) and adolescents (aged 16–19 years) that address transition issues. The groups will also explore how young children and adolescents prefer to receive health messages and health information (e.g., brochures, videos, podcasts, You Tube). These findings will inform the development of key messages tailored to the target audiences.

The discussion will focus on what messages or information about transition is important to communicate to young adults aged 16–19 living with hemophilia. A Moderator's Guide will be used to structure and facilitate the discussion in each group. The guides for these focus groups are included in Attachments 6 and 7.

Notes and audio recordings from the focus groups will be analyzed for common themes and divergent viewpoints. The analysis will highlight common themes or concerns that emerge from the focus groups. The results will be used to develop messages appropriate for the intended target audiences. Note that qualitative research has limitations and focus group results can be less generalizable. However, benefits to conducting focus groups for this particular study include the following: (1) focus groups will allow CDC to explore a range of ideas or feelings of the participants in regard to transition issues, (2) findings will allow CDC to better understand any differences between the different age groups, (3) focus groups will provide feedback on plans to develop educational materials, (4) focus groups allow for a moderator to probe participants on key messages, and (5) focus groups are a quick and cost-effective way of collecting this type of information.

Privacy Impact Assessment Information

(i) Why the information is being collected: The purpose is to get ideas and feedback from respondents on what messages or information about transition is important to communicate to adolescents (aged 16–19). The information gathered will be used to help develop and design a brochure, a factsheet, or other print materials that include key messages regarding transition tailored to the target audience.

(ii) Intended use of the Information: Intended uses include the following: (1) focus groups will allow CDC to explore a range of ideas or feelings of the participants in regard to transition issues, (2)

findings will allow CDC to better understand any differences between the different age groups, (3) focus groups will provide feedback on plans to develop educational materials, (4) focus groups allow for a moderator to probe participants on key messages**.**

Impact on Privacy to Respondents: The data collection efforts pose few, if any, risks to the respondents. Focus group participants will be asked their opinion on what messages or information about transition is important to communicate to adolescents (aged 16–19). The content of the discussion will focus on what information or messages are important to convey. The discussion topics are not sensitive and should not cause emotional stress or anxiety among the participants. The proposed data collection will have no effect on the respondent's privacy. A breach to participant privacy is a minor risk. An Informed Consent Form will be obtained from all of the participants before the discussion. At the beginning of the focus group, participants will be assured that any comments made during the focus group will not be attributed to them by name in any of the resulting reports. Participants will be reminded that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw from the focus group. To further safeguard participant information, transcriptionists will remove all references to each participant's identity beyond his or her first name, and all focus group tapes, notes, and transcripts will be destroyed when the project is completed. Furthermore, each recruiter, moderator, observer, notetaker, and transcriptionist will be asked to sign a *Privacy Protection Agreement* as shown in Attachments 10 and 11 as described above.

Section A.3. Use of Information Technology and Burden Reduction

None (zero percent) of the data collected will be collected using advanced information technology due to the nature of the focus group structure. The information will be gathered in person by an experienced focus group moderator meeting with 12 groups of nine participants each. Collecting the information in written form, through the mail or electronically, would not be effective in obtaining the kind of information required. The nuances of the information requested require face-to-face discussion, and fully understanding them depends on probes from an experienced moderator. Open-ended questions will be used to elicit opinions and reactions. To respond to the questions in the Moderator's Guide in writing would require long essay-type answers and be more time-consuming than in-person focus groups.

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

No evaluation of the 13,000 publications of the HANDI collection has ever been conducted. We have researched and conducted literature searches of databases and materials from CDC and NHF and other organizations. No comprehensive materials were found that address transition issues such as social support, health and lifestyles, educational/vocational/financial planning, self- advocacy and self-esteem, sexual health, and independent healthcare behaviors for the target audience of this study.

Section A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

Section A.6. Consequences of Collecting the Information Less Frequently

The consequence of not collecting the information would be to place an added burden on young children and adolescents with bleeding disorders by not providing materials that address transition issues. Although materials have been developed to guide parents and caregivers of newly diagnosed children and adolescents with bleeding disorders, considerably less attention has been given to developing materials for young children and adolescents, particularly materials that address transition issues. The many types of transitions for the person with a bleeding disorder include accepting the bleeding disorder, administering self-care, progressing through school, planning for a vocation or career, moving to an adult center, starting a family, experiencing middle age, and retiring. Transition

occurs throughout life for all people, but for those with chronic illness, it takes on additional significance. The collection of this information would allow for development of necessary materials to address the issues of transition for the intended audience.

Each respondent will be asked to respond only once.

There are no legal obstacles to reduce the burden.

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

This request fully complies with regulation 5 CFR 1320.5.

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

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* Attachment 2). The notice, as required by 5 CFR 1320.8 (d), was published on June 1, 2009 (volume 74, number 103, pages 26247–26248). No public comment was received in response to this notice.

B. From December 1, 2009, to January 31, 2010, the following list of representatives from several organizations outside of CDC were consulted and asked to review the data collection instruments for this study.

John A. Hermann
Institutional Review Board (IRB) Chair
ICF Macro
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
Telephone: 301–572–0340
E-mail: Jack.Hermann@sfr.fr

Neil Frick
Vice President for Research and Medical Information
National Hemophilia Foundation
116 West 32nd Street, 11th Floor
New York, NY 10001
Telephone: 212–328–3708
Fax: 212–328–3799
E-mail: nfrick@hemophilia.org

Maggie Gallarno
University of Mississippi Medical Center
350 West Woodrow Wilson Drive, Suite 3440
Jackson, MS 39213
Telephone: 601–984–2710
Fax: 601–815–5860
E-mail: Mgallarno@ped.umsmed.edu

Chasity L. Mullins
Vanderbilt University Medical Center
Hemostasis-Thrombosis Clinic
2200 Children's Way, 6105 DOT
Nashville, TN 37232-9830

Telephone: 615–936–1765
Fax: 615–936–8400
E-mail: Chasity.L.Mullins@vanderbilt.edu

Jean Marandola
George Clinic
Rhode Island Hospital
Potter, Room 159
593 Eddy Street
Providence, RI 02903
Telephone: 401–444–7731
Fax: 401–444–6104
E-mail: jmarandola@lifespan.org

Dr. Marion Koerper
University of California, San Francisco (UCSF) Hemophilia Program
350 Parnassus
Room 407
San Francisco, CA 94117
Telephone: 415–476–1280
Fax: 415–476–3301
E-mail: marionkoerper@sbcglobal.net

Regina Butler
Children's Hospital of Philadelphia
Hemophilia Treatment Center
34th Street and Civic Center Boulevard
Suite 439, Children's Seashore House
Philadelphia, PA 19104
Telephone: 215–590–2198
Fax: 267–426–2821
E-mail: butler@email.chop.edu

Casey Nakatani
16731 SE 311th Street
Auburn, WA 98092
Residence telephone: 253–981–4138
Cell telephone: 310–406–5639
E-mail: nakfam@gmail.com

Deborah Adamkin
Florida Hemophilia Association
18001 Old Cutler Road, Suite 501
Palmeto Bay, FL 33157
Telephone: 888–880–8330
Fax: 305–235–8281
E-mail: dadamkin@floridahemophilia.org

Rob Alexander
Central Ohio Chapter of NHF
834 West Third Avenue, Suite A
Columbus, OH 43212
Telephone: 614–429–2120
E-mail: ralexander@hemophilia.org

Ann Henningfeld
Hemophilia Foundation of Michigan
1921 West Michigan Avenue
Ypsilanti, MI 48197
Telephone: 734–544–0015
Fax: 734–544–0095
E-mail: anne@hfmich.org

Brent Movitz
2850 North Sheridan Road, Apt. 509
Chicago, IL 60614
Telephone: 248–821–0316
E-mail: brentmov@gmail.com

Marc Gilgannon
University of Virginia Medical System
Kluge Children's Rehabilitation Center
2270 Ivy Road
Charlottesville, VA 22902
Telephone: 434–924–5146
Fax: 434–924–0627
E-mail: mdg4n@hscmail.mcc.virginia.edu

Section A.9. Explanation of Any Payment or Gift to Respondents

Respondents will receive $75 for the session to ensure that sufficient numbers participate in the focus groups. The population being recruited for these focus groups is difficult to reach. Research has consistently shown the value of offering a modest remuneration for motivating respondents to participate in a research study: "Focus groups are unique from other data-gathering processes in terms of the investment that must be made by the individual. It is therefore no surprise that a tradition has been established to provide incentive for participation. From a practical aspect, it would be next to impossible to conduct focus groups without incentives in some situations. The incentive is not a reward and not really an honorarium or salary. It is an incentive. It serves as a stimulus to attend the session. The primary function of the incentive is to get the participants to show for the focus group—and to show up on time. The incentive serves to protect the promised time slot from being preempt."[1] The IRB approval of the study (see *IRB Findings and Approval* Attachment 13) included the review and approval of this level of remuneration.

Section A.10. Assurance of Confidentiality Provided to Respondents

[1] Krueger RA, Casey MA. Focus groups. A practical guide for applied research. Thousand Oaks (CA): Sage; 2009.

The proposed data collection will have no effect on the respondent's privacy. Breach of participant privacy is a minor risk. An Informed Consent Form (see Attachments 8a, 8b, and 9) will be obtained from all of the participants before the focus group discussion. At the beginning of the focus group, participants will be assured that any comments made during the focus group will not be attributed to them by name in any of the resulting reports. Participants will be reminded that their participation is voluntary and that they may choose to withdraw at any time without penalty or loss of benefits.

The recruiter in each city will obtain identifiable data on each participant's name, race/ethnicity, age, gender, mailing address, and phone number and determine whether he or she has participated in any focus group in the past. Identifiable data will be used by the recruiting firm to mail out a confirmation letter verifying the person's participation and providing the exact date, time, and location of the focus group. CDC, NHF and ICF Macro will not have access to the subjects' names or addresses.

The ICF Macro project director will communicate with each of the recruitment firms the importance of maintaining the security of the data. Each recruitment firm will be required to sign a privacy protection agreement (see Attachment 10). In addition, CDC will require that the following personnel read and sign protection agreements:

- Participant recruiters (Attachment 10)
- Moderators, note takers, and observers (Attachment 10)
- Transcriptionists (Attachment 11)

The ICF Macro project director will retain copies of the signed Informed Consent Forms. The forms will be kept in a locked file cabinet for up to three years following the study and then destroyed. The information on the forms will not be shared with anyone else.

To further safeguard participant information, transcriptionists will remove all references to each participant's identity beyond his or her first name, and all focus group tapes, notes, and transcripts will be destroyed when the project is completed.

Institutional Review Board Approval

The Moderator's Guides; Informed Consent Forms; Participant Screener and Recruitment Scripts; Recruitment Flyers; and the Privacy Protection Agreement for Focus Group Recruiters, Moderators, Note Takers, Observers, and Transcribers have been reviewed and approved by the corporate Institutional Review Board (IRB) of ICF Macro, the selected contractor. The IRB review and approval process ensures that issues relating to human subjects are addressed quickly and efficiently and that CDC adheres to the highest possible standards of evaluation. A copy of the IRB findings and approval can be found in Attachment 13.

Privacy Impact Assessment Information

A. Yes, this data collection effort is subject to the CDC Privacy Act System in accordance with CDC's System of Records Notice (SORN) #09-20-0136 Epidemiologic Studies and Surveillance of Disease Problems, Department of Health and Human Services/CDC/National Center for Infectious Diseases. (See *Privacy Act Checklist* Attachment 14).

B. All data (hard copy and electronic) will be stored at ICF Macro, CDC's selected contractor. All study materials (tapes and research notes) will be properly filed, maintained, and secured in a locked file cabinet. Electronic data will be kept on contractor's secured server, which is password protected and in a secured location with restricted physical access. Screener guides will be requested from the recruiting firms and destroyed by the research team once information collected from screener is moved to an aggregated form.

C. An Informed Consent Form will be obtained from all of the participants participating in the focus group (see Attachments 8a, 8b, and 9). Participants under age 18 will be required to submit a parent/guardian consent form prior to participating in the focus group (see Attachment 8b). Consent forms will be completed before the focus group begins. Project staff will be available to answer any questions that the participants may have prior to the beginning of the focus group. At the beginning of the focus group, participants will be assured that any comments made during the focus group will not be attributed to them by name in any of the reports resulting from this research. See Consent Forms for both youth (Attachment 8a) and for 18-19 year olds (Attachment 9).

D. Further, the participants will be reminded that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw from the focus group. Should they decide to withdraw from the focus group discussion, they will still receive their $75 cash incentive. The moderator will also orally present relevant information about the study to the participants to further enable them to make informed decisions about their involvement in the study. Respondents will be informed during the screening process that all notes and transcripts from the data collection will solely be used to write the final report. All of the transcripts and notes from the focus groups will only be available to the project staff. In addition, this information will also be disclosed to the respondents in the informed consent form. The legal authority to collect and maintain this data is granted by Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)) subject to the CDC Privacy Act System in accordance to the CDC's System of Records Notice (SORN) #09-20-0136 Epidemiologic Studies and Surveillance of Disease Problems, Department of Health and Human Services/CDC/National Center for Infectious Diseases.

Section A.11. Justification for Sensitive Questions

Depending on a person's background and experiences, questions involving hemophilia and living with hemophilia always have the potential to be sensitive and to raise emotional issues and memories. To address this issue of sensitivity, the focus groups will be conducted by two professionally trained moderators who have experience in working with parents, adolescents, and specialized populations (e.g., people with blood disorders). In addition, CDC staff and NHF staff will be observing the groups and will be available to address any sensitive issue as it relates to hemophilia and transition issues. Without this information, CDC cannot address the gaps in informational materials on transition issues for people living with hemophilia. CDC will use this information to develop a brochure, a factsheet or other print materials on transition issues for the target audiences.

An Informed Consent Form will be obtained from all of the participants before the discussion. At the beginning of the focus group, participants will be assured that any comments made during the focus group will not be attributed to them by name in any of the reports resulting from this research. Participants will be reminded that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw from the focus group for any reason and without penalty.

Section A12. Estimates of Annualized Burden Hours and Costs

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					
TOTAL		**336**	**—**	**—**	**197**

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							
TOTAL		**336**		**—**	**197**	**—**	**$4,004**

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

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

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

Section A.14. Annualized Cost to the Government

The average annualized cost to the Government to collect this information is $171,076 for the one-year OMB approval period that is requested. However it is noted here that this is a multi-year project (the total project period including both the data collection period (year 1) and post-data collection period (years 2 and 3) is a total of 3 years). Since we are requesting only a 1-year OMB approval period, the entire costs of the 3-year project are included in the 1-year OMB approval period "annualized cost" calculation.

		Total ($)
Federal Government Personnel costs	CDC Project Officer	2,966
	CDC Co-Principal Investigator	2,000
Contractor Direct Labor	Tasks 1–9	21,778
	Tasks 10–15	22,956
	Tasks 16–18	14,550
Other Contractor Direct Cost	Subcontractors, contract labor, travel and subsistence, office expenses	28,898
Total Indirect Cost	Fringe, overhead, general and administrative, fee	77,928
Total		$171,076

Section A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

Section A.16. Plans for Tabulation and Publication and Project Time Schedule

It is anticipated that participant recruitment will begin 2 to 3 weeks following OMB approval and that it will take approximately 4 weeks to recruit the full complement of participants in each site. Focus groups will be conducted 4–6 weeks after recruitment is complete. At the conclusion of all 12 focus groups, the notes and audio recordings from the focus groups will be analyzed for common themes and divergent viewpoints. The analysis will highlight common themes or concerns that emerge from the focus groups. A final report will be written that will include a discussion of the methodology used, findings, and recommendations. The analysis and report will be completed 12 weeks after the final focus group is conducted. The results of the research conducted will be used to develop manuscripts for publication in peer-reviewed journals.

For this research study, DBD/NCBDDD/CDC is requesting a 1-year data collection clearance. Below is a detailed project timeline.

A.16.—Project Time Schedule		
Formative Research		
Activity	**Timeframe**	
Identify and Recruit Participants	Recruitment Statistics Summary Report	1–2 months after OMB approval
	Conduct focus groups	3–4 months after OMB approval
	Notes/transcripts/audiotapes from formative research	5 months after OMB approval
Analyze and Report Data From Formative Research	Draft Report	6 months after OMB approval
	Final Report	7 months after OMB approval
Develop Message Concepts	Draft Message Concepts	8 months after OMB approval
	Final Message Concepts	9 months after OMB approval

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

NA

Section A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

1A. Public Health Service Act, 42 USC Sec. 241
1B. Child Health Service Act
2. 60-day Federal Register Notice
3. Participant Screener and Recruitment Script for Young Adults Aged 16–17
4. Participant Screener and Recruitment Script for Young Adults Aged 18–19
5. Participant Screener and Recruitment Script for Parents of Children Aged 5–12 or Parents of Teens/Young Adults Aged 16–19 Living With Hemophilia
6. Moderator's Guide: HANDI Focus Groups—Young Adults Aged 16–19 With Hemophilia
7. Moderator's Guide: HANDI Focus Groups— Parents of Children Aged 5–12 or Parents of Teens/Young Adults Aged 16–19 Living With Hemophilia
8a. Informed Consent Form for Youth
8b. Informed Consent for Parents of Youth under 18
9. Informed Consent Form for Youth 18–19
10. Privacy Protection Agreement for Focus Group Recruiters, Moderators, Note Takers, and Observers
11. Privacy Protection Agreement for Transcribers
12. Recruitment Flyers
13. IRB Findings and Approval
14. Privacy Act Checklist
15. 30-day Federal Register Notice