Supporting Statement Part A

for

FOCUS GROUP STUDY
FOR RAISING PUBLIC AWARENESS OF DEEP VEIN THROMBOSIS/PULMONARY EMBOLISM

New Request

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A. Justification

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 two years. The Division of Blood Disorders, located within the National Center on Birth Defects and Developmental Disabilities, implements health promotion and wellness programs designed to prevent secondary conditions in people with bleeding and clotting disorders. NCBDDD is making this request 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

There are few public health problems as serious as deep vein thrombosis (DVT) and pulmonary embolism (PE), yet these conditions receive little attention. DVT/PE is an under diagnosed, serious, preventable medical condition that occurs when a blood clot forms in a deep vein. These clots usually develop in the lower leg, thigh, or pelvis, but they can also occur in the arm. In more than one third of people affected by DVT, clots can travel to the lungs and cause PE, a potentially fatal condition.

The precise number of people affected by DVT/PE is unknown, but estimates range from 300,000 to 600,000 annually in the United States. DVT/PE is associated with substantial morbidity and mortality: One third of people with DVT/PE will have a recurrence within 10 years and one third of people die within 1 month of diagnosis. Among people who have had a DVT, one third will have long-term complications (post-thrombotic syndrome), such as swelling, pain, discoloration, and scaling in the affected limb. In some cases, the symptoms can be so severe that a person can become disabled. More troubling, sudden death is the first symptom in about one quarter of people who have a PE.

The Division of Blood Disorders submitted questions to the 2007 *HealthStyles* survey to determine the public's knowledge of DVT, its common symptoms, and risk factors. Although over 60% of respondents identified pain and swelling as symptoms, 60% did not identify tenderness (often the first sign of DVT) as a symptom. Only 38% of respondents knew that a DVT was a blood clot in a vein, and most could not identify common risk factors for DVT such as sitting for a long period of time (e.g. during air travel); having a leg or foot injury; having a family member who has had a DVT; taking birth control pills; or getting older; and certain groups could not identify risk factors that specifically applied to their risk. The results of this survey demonstrate the need for greater awareness of DVT, and its risk factors and the data show that there are many opportunities to develop audience specific messages that are age specific and culturally appropriate.

Much of the morbidity and mortality associated with DVT/PE can be prevented with early and accurate diagnosis and management. DVT/PE is preventable. It is important for people to be able to recognize the signs and symptoms and know when to seek care and available treatment. Individuals, families, and their support communities can reduce their risk by understanding DVT/PE and its risk factors. DVT/PE affects people of all races and ages. Many of the acquired risks such as obesity, advanced age, air travel, chronic diseases, cancer, and hospitalization are increasing in the United States, and we can expect to see increasing numbers of people affected by DVT/PE.

The CDC's Division of Blood Disorders will conduct focus groups to develop messaging concepts that will be used in a public awareness campaign to build knowledge and awareness of DVT/PE; increase recognition of the symptoms and risk factors for DVT/PE; and empower people to take action.

The project will address these objectives in two stages: in the first stage the Contractor will conduct eight (8) formative focus groups with nine (9) participants in each focus group to explore consumer knowledge, attitudes, and beliefs (KABs) toward DVT. Message concepts will be developed from insights emerging from this exploratory research phase. Westat will conduct eight (8) focus groups with nine (9) participants in each focus group during the second stage to test the message concepts and identify possible ways to present them.

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:

- Current awareness, feelings, levels of concern, and past experiences regarding DVT
- Language participants use to talk about DVT and blood clots
- DVT information needs of target audience
- Messaging barriers, such as if participants feel the condition is "not serious"
- Actions that are likely to result from increased awareness of DVT
- Preferred channels for receiving DVT information
- Preferred messengers for receiving DVT information
- Preferred timing for receiving DVT information

The project will collect data in two stages: the first stage will conduct formative research to explore consumer knowledge, attitudes, and beliefs (KABs) toward DVT. A total of 8 formative focus groups with the target audiences are scheduled for August/September 2011 in four cities: Atlanta, GA; Baltimore, MD; Pittsburgh, PA; and Tampa, FL. Each focus group will consist of nine (9) participants.

Message concepts will be developed from insights emerging from this exploratory research phase. The second stage will test the message concepts and identify possible ways to present them. A total of 8 message testing focus group are scheduled for September/October 2012 in four cities: Atlanta, GA; Baltimore, MD; Pittsburgh, PA; and Tampa, FL. Each focus group will consist of nine (9) participants. In-person focus groups will target two demographic audiences: (1) seniors (aged 65+); and (2) adults (25-64) who have been recently hospitalized.

For more details about the segmentation design, please see Table 1.

Table A.1. Segmentation Design

Focus group	Number of formative groups	Number of messaging groups	Composition
Persons hospitalized in last 12 months: surgery, birth, trauma (falls, car accidents), cancer treatment	2	2	Males, race/ethnicity mix, mix of ages 25-64
Persons hospitalized in last 12 months: surgery, birth, trauma (falls, car accidents), cancer treatment	2	2	Females, race/ethnicity mix, mix of ages 25-64
Older adults	2	2	Males, race/ethnicity mix, ages 65+
Older adults	2	2	Females, race/ethnicity mix, ages 65+

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 6 new instruments to be used for research to develop messaging concepts that will be used in a public awareness campaign to build knowledge and awareness of DVT/PE; increase recognition of the symptoms and risk factors for DVT/PE; and empower people to take action. The instruments include:

1. *Participant Screener for Recently Hospitalized Adults 25-64* (Attachment 3)
2. *Participant Screener for Seniors 65-80* (Attachment 4)
3. *Participant Rescreener for Recently Hospitalized Adults 25-64* (Attachment 5)
4. *Participant Rescreener for Seniors 65-80* (Attachment 6)
5. *Moderator's Guide: Formative Research Focus Groups* (Attachment 7)
6. *Moderator's Guide: Message Testing Focus Groups* (Attachment 8)
7. *Informed Consent Form* (Attachment 9)

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

Overview of the Data Collection System

CDC will collect qualitative data through in-person focus groups. The data will be collected via the 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.

The Contractor will work with CDC to identify and recruit focus group participants. Formative research participants will include seniors (aged 65-80) and adults (aged 25-64) who have been hospitalized in the last year. Message testing participants will include seniors (aged 65-80) and adults (aged 25-64) who have been hospitalized in the last year. Participants will be recruited to participate in one of sixteen in-person focus groups that will be conducted in the following cities:

- Atlanta, Baltimore, Pittsburgh, and Tampa (for the formative research task), and
- Atlanta, Baltimore, Pittsburgh, and Tampa (for the message testing task)

There are no costs to the respondents other than their time.

Data Collection Partners: Upon completion of each focus group, the audiotapes will be sent to IGI Associates, 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 Westat, 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: All tapes and transcripts will be destroyed after completion of the project, which is currently scheduled for April 2013.

Westat will work with professional focus group facilities to identify and recruit focus group participants. 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: Atlanta Outloud: 2801 Buford Highway NE, Suite 250, Atlanta, GA 30329
Telephone: 404-636-9054; Fax: 404-636-8927

Baltimore: Baltimore Research: 8320 Bellona Avenue, Suite 220, Baltimore, MD 21204
Telephone: 410-583-9991; Fax: 410-583-9992

Pittsburgh: FCP Research: 2101 Greentree Rd, Suite A-106, Pittsburgh, PA 15220

Telephone: 412-279-5900; Fax: 412-279-5148

Tampa: L&E Research, 100 North Tampa Street, Suite 3700, Tampa, FL 33602
Telephone: 877-344-1574; Fax: 813-443-8205

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 meet the screening criteria (see Attachments 3 and 4). 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 Westat and the CDC after removing information in identifiable form (IIF) such as their last name, phone number, and address. Upon arrival at the facility, participants will be asked to complete a paper-and-pencil re-screener to verify the accuracy of the recruit (see Attachments 5 and 6). Participants will only provide their first name during the focus group discussions and on the re-screener.

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.

A.2. Purpose and Use of the Information Collection

The CDC's Division of Blood Disorders will conduct focus groups to develop messaging concepts that will be used in a public awareness campaign to build knowledge and awareness of DVT/PE; increase recognition of the symptoms and risk factors for DVT/PE; and empower people to take action. These findings will inform the development of key messages tailored to the target audiences.

The discussion guide will begin with an introduction from the moderator and an icebreaker question to build rapport among participants. The discussion guide will contain open-ended questions that address the topics identified in Section A.1. To provide variety and a mix of cognitive tasks for participants during the groups, the guides will include a mix of group discussion and written exercises. 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 7 and 8.

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 are not 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 DVT/PE, (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 develop messaging concepts that will be used in a public awareness campaign to build knowledge and awareness of DVT/PE; increase recognition of the symptoms and risk factors for DVT/PE; and empower people to take action. As discussed in Section A.1 Background, DVT/PE receives little attention, yet it is a serious, preventable condition. Prior research demonstrates low levels of awareness about DVT/PE, its risk factors, and symptoms. The data show that there is an opportunity to develop audience specific messages that are age specific and culturally appropriate.

(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 DVT/PE, (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**.** The information gathered will be used to help develop messages that can be used in a brochure, a factsheet, or other health education materials about DVT/PE.

Impact on Privacy to Respondents: As noted in section A.1 above, no personal identifiable information collected will be transmitted to CDC. The only IIF being collected (respondent name, address, and phone number) is to be used by the focus group facilities (that will be hired by the contractor Westat) to screen potential respondents to determine eligibility for the focus groups. Therefore, the proposed data collection will have little or no effect on the respondent's privacy.

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 16 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.

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

CDC has made a significant effort to avoid duplication by conducting a literature review, conducted key informant interviews with experts who cited the need for greater public awareness of DVT/PE, data base searches, and participation in workshops and conferences. For example, during the stake holders meeting convened by the Office of the Surgeon General to assess the current state of DVT/PE one of the key recommendations for policymakers and government was to support the development of public awareness campaigns. Professional organizations such as the American Society for Hematology, Hemostasis and Thrombosis Research Society, and American Public Health Association have sponsored meetings or had sessions during meetings to specifically address the need for greater public awareness of DVT/PE. The proposed data collection is unique and does not duplicate any past, current, or planned information collection by other federal government agencies.

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

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort, and each respondent will be asked to respond only once. The consequence of not collecting the information would be to fail to effectively communicate with vulnerable Americans about a preventable condition that affects an estimated 300,000-600,000 people each year. The collection of this information would allow for development of effective health communication and education materials about DVT/PE.

There are no legal obstacles to reduce the burden.

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

This request fully complies with regulation 5 CFR 1320.5.

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

A. The 60 day Federal Register Notice was published on March 16th, 2011, pages 14400-14401, Volume 76, No. 51. No substantive comments were received.

B. Since October 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.

Elaine Eaker
Vice President
Westat
Phone: 301-610-8736
Email: elaineeaker@westat.com

Jennifer Berktold
Senior Study Director
Westat
Phone: 301-264-3964
Email: jenniferberktold@westat.com

Sharon Zack
Institutional Review Board (IRB) Chair
Westat
Phone: 301-610-8828
E-mail: sharonzack@westat.com

Leslie Brenowitz
Senior Vice President
GYMR Public Relations
Phone: 202-745-5112
Email: lbrenowitz@gymr.com

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. As an additional incentive to show up on time, participants that arrive at the facility 15 minutes before the scheduled time will be entered into a drawing for $50. 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 10) included the review and approval of this level of remuneration.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed and determined that the Privacy Act does not apply. Westat will hire a professional focus group facility to screen and schedule respondents. The only IIF that will be obtained are the participants' name and phone numbers for setting up interview appointments, which will be maintained at the focus group facility in its proprietary files. These personal identifiers will not be linked to data. During the focus groups, only first names will be used. Focus groups will be audio taped and transcribed for use by the Westat research team in developing a report. The audio tapes will be stored in a locked file cabinet, accessible only to project staff. The recording will be destroyed at the end of the study, which is currently scheduled for April 2013.

Institutional Review Board Approval: Westat's Institutional Review Board (IRB) reviewed the study instruments and granted approval for the study due to minimal risk (see Attachment 10). The study was approved by the IRB on January 3, 2011. Activity is research involving identifiable human subjects, but CDC involvement does not constitute "engagement" in the research. This project is conducted under a grant or cooperative agreement and

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

CDC employees will not interact with living individuals for research purpose and CDC will not obtain individually identifiable private information. The Contractor will be reviewed by an IRB with an FWA number.

Privacy Impact Assessment Information

A. The NCBDDD Privacy Officer has reviewed this submission and determined that the Privacy Act does not apply. Each focus group facility maintains its own list of individuals interested in participating in focus groups from which they will draw.

B. All data (hard copy and electronic) will be stored at Westat, 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 Attachment 9). 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.

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.

A.11. Justification for Sensitive Questions

The proposed research is voluntary, and no persons are required to participate. This voluntary aspect of the focus group is clearly stated in the informed consent and will be stressed by the moderator during the focus groups. 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.

There are no items considered to be highly sensitive for respondents. Participants may feel emotional discomfort from memories of an emotional or physical trauma that led to a hospital stay. However, the focus group discussion protocol does not contain questions that ask participants to share any aspect of their medical history with the group, and participants may refuse to answer any question they wish without penalty. The screener asks a series of questions about whether they have experienced clotting disorders such as stroke or DVT, but these questions are pertinent to the purposes of this study and the study's goals could not be accomplished without it.

One target audience is people who have been recently hospitalized—a group with elevated levels of risk for DVT—yet have not experienced DVT or PE. CDC wishes to get feedback from people recently at risk for DVT, yet who are not extremely familiar with DVT or PE, to better target health education messages about DVT.

A.12. Estimates of Annualized Burden Hours and Costs

It is estimated that a total of 144 respondents will have to be screened in order to recruit 36 focus group participants each year for two years. Each screening will take approximately 5 minutes. The re-screener will take approximately 9 minutes to complete. The estimated annualized response burden for the screening process is 12 hours.

The focus groups will have an average of nine participants each. Eight focus groups will be conducted each year with a total of 36 participants each year. Each focus group will take 90 minutes, for an annualized burden of 125 hours.

Table A.12.A. Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Seniors (65-80) Adults (25-64) recently hospitalized	Participant Screener	144	1	5/60	12
Seniors (65-80) Adults (25-64) recently hospitalized	Participant Re-screener	36	1	9/60	5
Seniors (65-80) Adults (25-64) recently hospitalized	Moderator's Guide: Formative Research Focus Groups (YEAR 1)	72	1	1.5	108
Seniors (65-80) Adults (25-64) recently hospitalized	Moderator's Guide: Message Testing Focus Groups (YEAR 2)	72	1	1.5	108
TOTAL			**—**	**—**	**125**

The annualized cost burden is shown in Table A.12B. The mean hourly wage rate is based on the most recent (2009) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $20.90. We have revised it slightly and rounded this number to $21.00. See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

Table A.12.B. Estimated Annualized Burden Costs

Type of Respondent	Survey Instruments	Number of Respondents	No. Responses per Respondent	Annual Burden (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Seniors (65-80)	Participant Screener	144	1	5/60	12	$21.00	$252
Adults (25-64) recently hospitalized							
Seniors (65-80)	Participant Re-screener	36	1	9/60	5	$21.00	$105
Adults (25-64) recently hospitalized							
Seniors (65-80)	Moderator's Guide: Formative Research Focus Groups (YEAR 1)	72	1	1.5	108	$21.00	$2,268
Adults (25-64) recently hospitalized							
Seniors (65-80)	Moderator's Guide: Message Testing Focus Groups (YEAR 2)	72	1	1.5	108	$21.00	$2,268
Adults (25-64) recently hospitalized							
Total							**$2,625**

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 Federal Government to collect this information is $177,783 per year for two years. We are requesting OMB approval for a two-year project; this estimate is based on eight exploratory focus groups in Year 1, and eight message testing focus groups in Year 2, and cost of the Federal Project Officer who is responsible for the management and oversight of the project (see Table A.14). These figures include the costs of study design, materials development, facility rental, participant tokens of appreciation, data collection, analysis, and report writing.

Table A.14. Cost to Government

		Year 1	Year 2	Total
Federal Government Personnel costs	CDC Project Officer (GS-13/10 at 5%)	$5,500	$5,500	$11,000
Contractor Direct Labor	Base Year: Tasks 1–6	$40,894	$0	$40,894
	Option Year: Tasks 1–6	$0	$32,158	$32,158
Other Contractor Direct Cost	Subcontractors, contract labor, travel and subsistence, office	$71,447	$60,333	$131,780

	expenses			
Total Indirect Cost	Fringe, overhead, general and administrative, fee	$79,024	$63,709	$142,733
Total		$196,865	$161,700	$358,565

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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 2 weeks to recruit the full complement of participants in each site. Focus groups will be conducted 1–2 weeks after recruitment is complete. At the conclusion of 8 focus groups, 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. From the formative analysis, message concepts will be developed. A second round of 8 focus groups will be conducted to test and refine the message concepts. A final report will be written that will include a discussion of the methodology used, findings, and recommendations for the final message concepts. The analysis and report will be completed 16 weeks after the final focus group is conducted.

For this research study, DBD/NCBDDD/CDC is requesting a 24 month data collection clearance. Below is a detailed project timeline (Table A.16).

Table A.16. Project Time Schedule

Activity	**Timeframe**
Conduct Formative Research	
Recruitment Statistics Summary Reporting	1 months after OMB approval
Conduct focus groups	2 months after OMB approval
Notes/transcripts/audiotapes from formative research	4 months after OMB approval
Analyze and Report Data From Formative Research	
Draft Report	7 months after OMB approval
Final Report	9 months after OMB approval
Develop Message Concepts	
Draft Message Concepts	12 months after OMB approval
Final Message Concepts*	21 months after OMB approval
Conduct Message Testing Research	
Recruitment Statistics Summary Reporting	14 months after OMB approval
Conduct focus groups	15 months after OMB approval
Notes/transcripts/audiotapes from formative research	17 months after OMB approval

Analyze and Report Data From Message Testing Research	
Draft Report	20 months after OMB approval
Final Report* (will include Final Message Concepts)	21 months after OMB approval

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

Not applicable. The OMB expiration date will be displayed.

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

There are no exceptions to the certification.