

Supporting Statement A

for

Formative Research to Support the Development of Sickle Cell Disease Educational Messages and Materials for the Division of Blood Disorders

Request for Reinstatement

JoAnn M. Thierry, PhD
Team Leader
Prevention Research Team
Division of Blood Disorders
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention
1600 Clifton Road, MS E-64
Atlanta, GA 30333
Jxt4@cdc.gov
Phone: 404-498-6730
Fax: 404-498-6799

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Attachment 2: 60- Day Federal Register Notice

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Background

This Information Collection Request is submitted under the classification “Reinstatement.” The length of data collection requested for OMB-PRA approval is one year. The Division of Blood Disorders, located within the National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC), is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; Attachment 1).

Working with community-based organizations, the Prevention Research Team in the Division of Blood Disorders seeks to address the need for educational messages and materials for adolescents, young adults, adults, and older adults living with sickle cell disease (SCD). To effectively reach these populations with culturally relevant messages and materials, it is important to fully understand and reflect the needs and desires of the target audiences.

SCD is a genetic disease that occurs in 1 of every 500 African American births in the United States, as well as other populations in the U.S., including Hispanic Americans and other emerging populations. People living with SCD often have episodes of extreme pain, damage to vital organs, and in the recent past, shorter life spans.

With advances in scientific research and treatments, people with SCD are now living longer and SCD is no longer simply a pediatric disease. Adolescents and young adults need to be prepared for the transition from pediatric care, where they typically have minimal responsibilities for arranging for their care, to adult care, where they must assume full responsibility for their health care and disease self-management. Adults and older adults face additional challenges coordinating their care among providers, handling relationships and starting a family, and managing changes to their health in combination with their SCD. To improve the quality of life of people living with SCD, there is an immediate need to provide effective materials for adolescents, young adults, adults, and older adults.

The purpose of this project is to develop new messages and materials for adolescents, young adults, adults, and older adults living with SCD. In particular, this project seeks to develop messages and materials that meet the needs of these audiences and fill a gap in existing materials related to the adoption of healthy behaviors and the prevention of complications associated with sickle cell disease. Within the broad goals of the project described above, the specific aims of the formative research are:

- Identify informational needs of the intended audiences.
- Identify media preferences of the intended audiences.

As a first step in the message and materials development process, the CDC has charged the American Institutes for Research (AIR) with conducting formative research activities – an environmental scan of existing materials and focus groups with people with SCD. This document addresses the collection of qualitative data through focus groups. The environmental scan will provide an understanding of what SCD materials are available to patients. This includes identifying key health messages, formats, the extent to which materials cover relevant age groups, and the gaps in information, target audiences, or messages. To identify media preferences, informational needs, and responses to existing messages, formative focus groups with four target audiences will be conducted.

Privacy Impact Assessment Information

i. Overview of the Data Collection System

CDC will collect qualitative data through in-person and telephone focus groups. A total of 10 focus groups will be conducted. Each focus group will be conducted with eight to nine participants and will last 2 hours. The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. The focus groups will be audiotaped with the permission of each participant. Upon completion of each focus group, the audiotapes will be sent to a professional transcription company that will produce transcripts. All AIR staff are required to complete Human Subjects Protection training. Non-AIR staff (e.g., moderators, transcriptionists, etc., will be required to sign a Privacy Protection Agreement (Attachment 3). When the electronic versions of the transcripts are returned to AIR, the moderator will edit each transcript to remove all references to each participant's identity beyond his or her first name. The audiotapes (and other related data) will be stored on AIR's computer system, in password protected directories. The audio files will be destroyed after transcripts have been prepared.

ii. Items of Information to be Collected

During the screening process, AIR will collect data including the participants' name, address, phone number, race/ethnicity, age, education level, and type of SCD. This information will be used 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. Participant demographics will be summarized in focus group reports. Individual identifiers that would permit identification of a respondent will be deleted from data files stored on AIR's computer system.

The following information will be collected during focus groups:

- Informational needs of the intended audiences:
 - When are the most appropriate times to receive this information?
 - What does each audience need to know about SCD to reduce the risk of complications and to facilitate more effective disease self-management?
 - To what extent do existing messages and materials address the target audiences' needs?
- Media preferences of the intended audiences:
 - How (in what format) does each audience prefer to receive information?
 - Who does each audience prefer to receive information from?

iii. 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; will not refer respondents to a website; and will not involve children under 13 years of age.

A.2. Purpose and Use of Information

The CDC's Division of Blood Disorders and its contractor, AIR will conduct a total of 10 focus groups to gather information that will be used to design educational materials for people with SCD in the following age groups: adolescents (15-17), young adults (18–25), adults (ages 26–35), and older adults (ages 36+). Data will be collected only once for each participant in the focus groups. The materials will address adoption of healthy behaviors and the prevention of complications associated with sickle cell disease. The groups will also explore how people with SCD prefer to receive health messages and health information (e.g., brochures, videos, podcasts, and social media). These findings will inform the development of key messages tailored to the target audiences.

The focus groups will identify messages or information about preventing complications and staying healthy that are important to communicate to people with SCD. A moderator's guide will be used to structure and facilitate the discussion in each group. The guides will be tailored by audience and are included as Attachment 4. The consequence of not collecting the information would be to place an added burden on people with SCD by not providing materials that address issues related to preventing adverse complications and outcomes. Previous research has indicated that a major factor in the increased number of people with SCD that experience life threatening illnesses can be attributed to the lack of knowledge about how to prevent or manage SCD complications.

2.1 Privacy Impact Assessment

The data collection efforts pose few, if any, risks to the respondents. Focus group participants will be asked about what kinds of information on self-management and prevention behaviors would be most useful to them and the best ways to present this information. 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. For minors aged 15-17, consent and permission will be obtained from parents and adolescents will be asked to provide written assent to participate. 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, note taker, and transcriptionist will be asked to sign a *Privacy Protection Agreement* as shown in Attachment 3.

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

A total of 10 focus groups will be completed. The information will be gathered in-person for eight of the 10 focus groups. The eight in-person groups will be held in four cities: Atlanta, GA; Detroit, MI; Oakland, CA; and Philadelphia, PA. Two of the 10 focus groups will be collected by using telephone focus groups and employing the use of a toll-free conference line. Telephone focus groups do not provide data which are as rich or detailed as in-person focus groups, nor do they create as powerful a group dynamic as in-person groups. However, the use of telephone technology will allow us to collect information from geographically disparate individuals who do not live in or near large population centers. This will inform about the SCD informational needs of individuals who live in such areas.

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 or verbal 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 focus groups.

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

To the best of our knowledge, there has been no research conducted to assess the informational needs of people with SCD that would enable the development of self-management and prevention messages that are tailored to specific, age-related target audiences. The National Heart Lung and Blood Institute collected information on SCD awareness campaigns in a media scan in 2009.¹ It was noted that:

In summary, the environmental scan found only a limited number of campaigns. The focus of these campaigns was primarily on general awareness, rather than treatment options, management, or prevention of SCD complications (p. 19).²

The Health Resources and Services Administration conducted a series of five focus groups with adults with SCD in 2010 to assess the gaps in information about access to care and needs of people and families with SCD and obtain recommendations for future works. Neither of these efforts dealt with identification of behaviors and strategies to promote the self-management of SCD and the avoidance of complications from SCD for targeted populations – the major informational goals of these focus groups.

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 study. There are no plans to repeat it. Data will be collected only once for each participant in the focus groups. The consequence of not collecting the information would be to place an added burden on people with SCD by not providing materials that address issues related to preventing adverse complications and outcomes. The collection of this information would allow for development of necessary materials to address the issues of healthy behaviors and preventive activities for the intended audiences.

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

This request fully complies with the regulation 5 CFR 1320.5.

¹ American Institutes for Research (2009). *Sickle Cell Disease Awareness Campaigns: Media Scan 2004–2009*. Prepared for National Heart, Lung, and Blood Institute. Washington, DC: Author.

² U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute, (April, 2010), *Sickle Cell Disease Awareness and Education Strategy Development Workshop Report, Washington, D.C.: Author, Publication No. 56-205N.*

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 January 16, 2013 (volume 78, number 11, pages 3429 - 3430). No comments were received in response to this notice.
- B. This data collection effort has been developed in collaboration with several organizations outside CDC. The following list of representatives from these organizations were consulted and asked to review the data collection instruments for this study.

Marie Boyle

Public Health Advisor
National Heart, Lung, and Blood Institute
31 Center Dr, Bldg 31, 4A10F
Bethesda, MD 20892
(301) 594-1950
marie.boyle@nih.hhs.gov

R. Lorraine Brown, RN, BS

Public Health Analyst
Health Resources and Services Administration
5600 Fishers Lane, 18A-19 PKLN
Rockville, MD 20857
(301) 443-1080
lbrown@hrsa.gov

Carlton Haywood Jr., PhD, MA

Assistant Professor
Johns Hopkins Berman Institute of Bioethnics
624 N. Broadway, Hampton House, Room 355
Baltimore, MD
(410) 614-6335
chaywood@jhsph.edu

Lanetta B. Jordan, MD, MPH, MSPH

Director of Sickle Cell Services
(and CMO of the SCDA)
Memorial Healthcare System
Broward Hospital District
3501 Johnson Street
Hollywood, FL 33021
(954) 265-5805
ljordan@mhs.net

Roshni Kulkarni, MD

Professor and Director

Pediatric & Adolescent Hematology/Oncology
Department of Pediatrics and Human Development
Michigan State University
B215 Clinical Center
East Lansing, MI 48824
(517) 355-5039
roshni.kulkarni@hc.msu.edu

Elyse Mandell, APRN

Nurse Practitioner
International Association of Sickle Cell Nurses and Physician Assistants
Division of Hematology Brigham & Women's Hospital
75 Francis Street
Boston MA 02115
(617) 732-8485
emandell@partners.org

Shirley Miller

Sickle Cell Disease Association of America
P.O. Box 225602
Dallas, TX 75222
(214) 796-1639
shirleyrenee3@gmail.com

Claudia R. Morris, MD

Director of Fellowship Research
Pediatric Emergency Medicine Fellowship
Children's Hospital Oakland Research Institute in Oakland
747 52nd Street
Oakland, CA 94609
(510) 428-3000
cmorris@mail.cho.org

Monique Ndenecho, MPH

Public Health Advisor
National Heart, Lung, and Blood Institute
31 Center Drive, Bldg 31, 4A31
Bethesda, MD 20892
(301) 827-4877
monique.ndenecho@nih.hhs.gov

Janet Ohene-Frempong, MPH

President
J.O. Frempong & Associates
7097 Ronaele Drive
Elkins Park, PA 19027
(215) 460-7754
jofrempong@comcast.net

Allan Platt, PA-C, MMSc

Advanced Didactic Coordinator, Physician Assistant Program
Emory University School of Medicine
1460 Clifton Road, NE
Atlanta, GA 30322
(404) 727-7825
aplatt@emory.edu

Elna Saah, MD

Director of the Sickle Cell Disease Treatment Program
Michigan State University
138 Service Rd, # 110A
East Lansing, MI 48824
(517) 364-5440
elna.saah@hc.msu.edu

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

Respondents who participate in the 2 hour discussion will receive \$75.00 (\$37.50 per hour) as a token of appreciation for their interest. The population being recruited for these focus groups is difficult to reach. The Participant Screener and Recruitment Script include information on the incentive, as shown in Attachment 5. 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 an honorarium or salary. It is an incentive to motivate participation. 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 preempted.”¹

The IRB approval of the study (see Attachment 6) included the review and approval of this level of remuneration.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the NCBDDD Privacy Act Officer, who determined that the Privacy Act does not apply. Informed consent (see Supplementary Attachments 7, 8, and 9) will be obtained from all of the participants as part of the focus group, but before the focus group discussion commences. Participants under age 18 will be required to submit a parental permission form/consent prior to participating in 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 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. In addition, during the focus groups, participants will be identified by first name only, to minimize any risk of disclosure.

IRB Approval. This information collection has been determined not to involve research.

Privacy Impact Assessment Information

- A. This project will not maintain any individually identifiable information. 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)).
- B. All data (hard copy and electronic) will be stored at AIR, CDC's selected contractor. All study materials will be properly filed, maintained, and secured. The storage of hard copy media that includes identifiable information (audio tapes, video tapes, research notes, and transcriptions) or other sensitive project data will be stored in a lockable container inside a lockable office. Hard copy crosswalk files that map individual identifiable data to a de-identified code shall be stored in a separate folder/container from data required for research purposes.

Electronic data will be kept on contractor's secured server, which is password protected and in a secured location with restricted physical access. The storage of sensitive personal identifiers on local desktop hard drives is not authorized. De-identified information is not considered sensitive and can be emailed at the discretion of the user. Only valid business email accounts can be used to support messaging of project data. Email forwarders involving non-business email accounts shall not be used. For file transfer between staff or between staff and clients, external contractors, etc, arrangements shall be made to use only secure FTP (SFTP) services (provided by AIR).

Audio/video recordings will be destroyed as soon as possible at the end of the project. Data needs to be retained for a period of time up to 1 year after end of project at which time the data will be eligible for deletion/destruction and decided upon by final approval by the AIR project director. (e.g., after transcription or as per other client agreements).

- C. An informed consent form will be obtained from all of the participants before the discussion. For minors aged 15-17, consent and permission will be obtained from parents in advance of the group and adolescents will be asked to provide written assent to participate. 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. The informed consent, permission, and adolescent assent forms can be found in Supplementary Attachments 7, 8, and 9.
- D. At the beginning of the group discussion, participants will be reminded by the moderator 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 incentive. In addition, this information will also be disclosed to the participants in the informed consent, adolescent assent, and parental permission forms.

A.11. Justification for Sensitive Questions

Depending on a person’s background and experiences, questions involving SCD and living with SCD always have the potential to be sensitive and to include discussions of informational needs related to sexual behaviors. Since priapism is a common concomitant of SCD, it is not unreasonable that participants will express their desire for information to allow them to avoid or deal with this condition and to avoid subsequent complications. To accommodate the issue of dealing with sensitive topics, the focus groups will be conducted by trained moderators who have experience in working with adolescents (for the adolescent focus groups) and specialized populations (e.g., people with blood disorders). In addition, all individuals in each focus group will be of the same gender (as will be the moderator).

Without this information, CDC cannot address the gaps in informational materials on prevention of complications and behaviors to stay health for people living with SCD. CDC will use this information to develop messages and possibly, materials for the target audiences.

Informed consent will be obtained from all of the participants before the discussion (in the case of adolescents, parents will provide permission and consent and adolescents will provide assent). 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.

A.12. Estimates of Annualized Burden Hours and Costs

The CDC’s Division of Blood Disorders and it’s contractor, AIR will conduct a total of 10 focus groups to gather information that will be used to design educational materials for people with SCD in the following age groups: adolescents (15-17), young adults (18–25), adults (ages 26–35), and older adults (ages 36+). It is estimated that 120 respondents will have to be screened in order to recruit 90 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 up to nine participants each. Ten focus groups will be conducted, with a total of up to 90 participants. Each focus group will take 2 hours, for a total burden of 180 hours. The estimated annualized burden hours are 204. There is no cost to respondents other than their time.

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 15–17) living with SCD	Participant Screener and Recruitment Script	120	1	12/60	24
Young adults aged (18–25) living with SCD					
Adults (aged 26-35) living with SCD					
Older adults (aged 36+) living with SCD					

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Adolescents (aged 15-17) living with SCD	Focus Group Moderator's Guide	90 (10 groups x 9 participants per group)	1	2	180
Young adults aged (18–25 living with SCD					
Adults (aged 26-35) living with SCD					
Older adults (aged 36+) living with SCD					
TOTAL					204

Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate (\$)	Total Respondent Costs (\$)
Parents of adolescents (aged 15–17) living with SCD	Participant Screener and Recruitment Script	24	\$21.35	\$512.40
Young adults aged (18–25 living with SCD				
Adults (aged 26-35) living with SCD				
Older adults (aged 36+) living with SCD				
Adolescents (aged 15-17) living with SCD	Focus Group Moderator's Guide	180	\$21.35	\$3,843.00
Young adults aged (18–25 living with SCD				
Adults (aged 26-35) living with SCD				
Older adults (aged 36+) living with SCD				
TOTAL		204		\$4,355.40

Estimates of annualized cost to respondents

The hourly wage cost is based on the U.S. Department of Labor's "May 2010 National Occupational Employment and Wage Estimates," which lists the mean hourly wage for all occupations as \$21.35. See http://www.bls.gov/oes/current/oes_nat.htm#00-0000

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

There are no direct costs to respondents other than their time to participate in the study.

A.14. Annualized Cost to the Government

The total cost to the Federal Government for collecting and analyzing the data as described within this submission is \$176,918. The average annualized cost to the Government to collect this information is \$176,918 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 is three years and includes formative research through working group consultation and environmental scan (year 1), data collection period for which this OMB application covers (year 2) and post-data collection period (year 3) is a total of 3 years.

Since we are requesting only a 1-year OMB approval period, only the costs of data collection during the 1-year OMB approval period appear below in the “annualized cost” calculation. The table below shows the basic cost components.

Annualized Cost to the Federal Government

		Total (\$)
Federal Government Personnel Costs	CDC Technical Monitor GS13 (.05 FTE)	\$4,181
	CDC Public Health Team Leader GS15 (.03 FTE)	\$2,906
Grantee Direct Labor	Project Director (.01 FTE)	\$1,112
	Deputy Project Director (.11 FTE)	\$8,578
	Sr. Communications Specialist (.02 FTE)	\$1,924
	Sr. Researcher (.03 FTE)	\$2,231
	Research Associate (.14 FTE)	\$6,204
	Project Assistant (.09 FTE)	\$3,295
	Editor (.01 FTE)	\$400
	Publications Specialist (.01 FTE)	\$335
Personnel Cost Subtotal including Fringe		\$42,483
Other Grantee Direct Cost	Subcontractors & consultants	\$63,752
	Travel and subsistence	\$6,054
	Meeting costs/facilities	\$9,300
	Participant incentives	\$8,400
	Reproduction	\$208
	Teleconferences	\$81
Subtotal, Grantee Cost		\$123,191
Total Cost		\$176,918

A.15. Explanation for Program Changes or Adjustments

This is a request for reinstatement of a previously approved data collection. There are no changes or adjustments.

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

At the conclusion of all 10 focus groups, the notes and audio recordings from the focus groups will be analyzed for common themes and divergent viewpoints. 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. No complex analytical techniques will be used.

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

Project Time Schedule

Activity	Timeframe	
Identify and Recruit Participants	Recruitment Statistics Summary Report	3 months after OMB approval
	Conduct focus groups	4–6 months after OMB approval
	Notes/transcripts/audiotapes from formative research	7 months after OMB approval
Analyze and Report Data From Formative Research	Draft Report	8 months after OMB approval
	Final Report	9 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

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

There are no exceptions to the certification.