Formative Research, Messages, and Materials Development for NCBDDD

Supporting Statement A

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Title

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD), requests approval for a new generic information collection package that supports formative research, messages and materials development in birth defects and developmental disabilities; human development and disabilities; and blood disorders. Identified priority diseases, disorders, and conditions included in this information collection activity include but are not limited to preconception health; autism spectrum disorders (ASDs) and other developmental disabilities; fetal alcohol spectrum disorders (FASDs); neural tube defects (spina bifida, anencephaly); muscular dystrophy; fragile X; deep vein thrombosis/pulmonary embolism (DVT/PE); sickle cell disease (SCD); attention-deficit/hyperactivity disorder (ADHD); and Tourette syndrome. This is a new Information Collection Request and is authorized by Section 301, "Research and Investigation," of the Public Health Service Act (42 U.S.C. 241) **(Attachment A)**. The length of data collection requested for OMB-PRA approval is three years.

NCBDDD conducts formative research for developing new messages, materials, and strategies that respond to the changing epidemiology of the priority diseases and conditions of the three (3) health condition groups. A generic clearance mechanism would increase productivity of CDC programs and improve the quality of public health interventions and health communication programs. It is estimated that approximately 8 – 10 individual projects will be processed per year using this mechanism.

Background
The Children's Health Act of 2000 required the establishment of NCBDDD. The Center is organized into three divisions, which are focused on preconception health, birth defects and developmental disabilities; human development and disabilities; and blood disorders. NCBDDD promotes the health of babies, children and adults and focuses on identifying the causes of and prevention of birth defects and developmental disabilities; helping children to develop and reach their potential for full, productive living; and optimizing the health outcomes among people of all ages with disabilities. These goals are accomplished through research, partnerships, and prevention and education programs.

The behavioral, clinical, and surveillance projects implemented by NCBDDD are the foundation upon which recommendations and guidelines are revised and updated. Formative research is the mechanism by which evidence is obtained for priority diseases in these three (3) health condition groups and by which recommendations and guidelines are revised and updated.

The data collection and evidence are developed using a multitude of information sources including internal and external subject matter experts, field experience, consultation with external colleagues, piloting activities, and formal evaluations. The involvement of external and internal subject matter experts produces scientifically valid instruments, interventions, and methods that enable NCBDDD to be responsive to the changing epidemiology and community

needs of these priority diseases and conditions. Targeted audience members or representatives provide the information for developing clear and influential health messages, materials, and strategies that promote health and well-being. In order to reduce the burden of the priority diseases and conditions identified in this data collection effort, CDC invests in public education campaigns and social marketing strategies to integrate population-level interventions. An integrated research effort is needed to fill in gaps of knowledge, awareness, screening, and prevention behaviors and could simultaneously work to reduce stigma surrounding these topics within special populations, explore cultural issues, and increase the demand for and uptake of screening by health care providers.

Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments. These activities will be used to inform many aspects of surveillance, communications, health promotion, and research project development for the identified priority diseases, disorders, and conditions in the three health condition groups. The activities include the utility and acceptability of recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced. Overall, these development activities are intended to provide information that will increase the success of the surveillance or research project through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public.

1.1 Privacy Impact Assessment

Depending on the individual information collection request, information might be collected using the following modes: focus groups, in-person interviews (face-to-face or via telephone) **(Attachment E)**, paper-and-pencil questionnaires, or electronically **(Attachment F)**. Electronic modes include handheld devices, computer-assisted self-interviews, computer-assisted personal interviews, web-based surveys, or other point-of-service collection devices.

Any information in identifiable form (IIF) collected by partners would be unlinked or stripped from the database that is submitted to the CDC. Web-based methods for survey or intervention delivery may also be evaluated under this generic approval, and may involve the hosting of a website in order to conduct the evaluation. There will be no websites or internet content directed at children under the age of 13. Individual collection requests submitted under this generic approval will describe any web-based material involved.

I. Overview of the Data Collection System

It is estimated that approximately 8 – 10 individual projects will be processed per year using this mechanism. Data collection activities from a variety of groups are anticipated.

Attachments E and F include example moderator's guide and survey questions (respectively), that could be used in these data collection activities.

The types of information collection activities included in this generic package for NCBDDD's three (3) health condition groups are:

1) Qualitative interviewing will use volunteer respondents for exploratory and formative research, intervention methods, and the development of new messages, materials, and strategies. Interviews may be individual or group, conducted in-person, (face-to-face or telephone), or via the internet (e.g., internet focus groups). The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. The focus groups may be audiotaped with the permission of each participant. Results of qualitative interviews are used to develop population-appropriate methods, interventions, messages, materials, and strategies for current and future projects.

2) Cognitive interviewing and in-depth interviews may be conducted among the volunteer respondents. These may be individual interviews or focus group interviews. Cognitive interviews are commonly used for development and testing of specific data collection instruments and frequently involve several rounds of cognitive interviews with each iteration of the product. Results of cognitive interviews are used to make instrument design decisions that minimize response error and reduce burden to the public.

3) Quality control surveys may be conducted for recipients of educational information to ensure that health messages are accurate and appealing and meet the intended goals behind each message. These surveys may include in-person interviews, focus groups, paper-and-pencil surveys as well as online surveys.

4) Testing of new methodologies and materials may be conducted with participants using the enrollment, study methods and observations by experienced study methodologists. The purpose of testing methodologies and materials will be to assess project methods and materials not yet used by CDC or used on a limited scale. Information from testing can be used to improve methods, messages, materials, and strategies to reduce the burden of future data collections.

II. Items of Information to be Collected

Attachment C includes a partial list of the types of screening questions that could be used by the data collection activities in this request.

IIF such as name, address, medical information, referred individuals etc. may be collected. This information may be used for scheduling participants for focus groups or interviews, mailing confirmation letters verifying the person's participation, or mailing quality control surveys and providing the exact date, time and location of the any information collection activity.

Any IIF collected will be kept in a secure location and accessible only to the interviewer and/or specifically designated staff. Strict access controls will be put in place to ensure the integrity of collected data. This information will be destroyed when the project has ended.

The databases created for CDC to contain information collected as part of this request will not include personal information. Line listings of participants when used will utilize a project-generated identification number independent of any personal identity of the participants.

Because this request includes a wide range of studies, individual data collection requests will include items of information to be collected and copies of the data collection instruments.

III. Identification of Websites and Website Content Directed at Children Under 13 Years of Age

Web-based methods for surveys may involve the creation of a website with controlled access. Web-based investigations will include surveys and components of formative research collecting public evaluations of health communication messages or materials. Under no circumstances will CDC-sponsored websites be directed at children under 13 years of age. Individual collection requests submitted under this generic approval will describe any web-based material involved.

A.2. Purpose and Use of Information Collection

Because of CDC's need to respond rapidly to changes in the epidemiology of NCBDDD's identified priority diseases and conditions through development of new projects, the exact nature of every activity is not always known until just prior to the need for its development. It is most likely that a combination of the listed studies will be employed. For example, when developing an instrument, focus groups and interviews may provide the information to make the changes which then would need to be tested both qualitatively and quantitatively to ensure that the changed instrument is acceptable to the targeted audience but is also more efficient than the existing version in providing the needed information.

- CDC's ability to process and/or integrate information into an on-going national program in a timely manner is critical to its success. Formative research is an integral part of the research, surveillance, and health communication activities of NCBDDD because program staff depend on the results to monitor changes in disease epidemiology and are able to design better and more effective interventions, methods, messages, and materials.
- None of the studies proposed intend to produce results that can be generalized beyond the scope of each study. The objective of this request is to enable NCBDDD to improve the quality of programs and the quality of data collection systems and to respond to the needs of the affected persons and the community in a timely manner. The improved timeliness of this information collection will improve data and program quality, increase the efficiency of data collection, and decrease burden to the public.

2.1. Privacy Impact Assessment Information

(i) Why the information is being collected

The information is being collected in order to ensure that CDC has accurate and up-to-date information to use to develop messages, materials, and strategies regarding NCBDDD's identified priority diseases, disorders, and conditions.

(ii) Intended use of the Information

The findings from the information collection will be used to ensure that our messages, materials, and strategies are accurate and reflect findings from the formative research. Findings about materials and program development may be published in general literature. Findings will also allow CDC to better understand any cultural differences and health disparities and will provide information about the quality of existing materials and thus generate information about how to further improve materials and programs.

(iii) Impact on Privacy to Respondents: The only IIF being collected (respondent name, address, and phone number) is to be used for logistical purposes, such as by focus group facilities to screen potential respondents to determine eligibility, or similar processes of selecting and contacting suitable respondents for participation. No IFF will be passed on at any point. Survey data plus limited demographic information may be delivered to CDC along with a participant ID. The participant ID will be non-identifying and will not be linked to any personal information that may be delivered to CDC. Therefore, the proposed data collection will have little or no effect on the respondent's privacy.

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

Information collection may be conducted using the most current modes of survey data collection, including web-based surveys. Though these technologies will be used by many of the individual projects in this data collection, the nature of many of these proposed activities typically requires direct interaction between respondents and project staff, especially in the case of qualitative interviewing and cognitive testing. Data collections to be conducted under this generic package will provide detailed information about the proposed data collection tools and how they use information technology when feasible to reduce burden.

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

CDC has three generic collections that are related to the proposed collection. The NCHS Laboratory-based Questionnaire Research (OMB Control Number 0920-0222, expiration 6/30/2015) provides survey questionnaire development and testing based on cognitive interviewing methodology to be used in CDC, other federal agencies, or other academic or professional institutions. The CDC and ATSDR Health Message Testing System (OMB Control Number 0920-0572, expiration 2/28/2015) is designed to refine message concepts and to test draft materials for clarity, salience, appeal, and persuasiveness with external audiences. The NCHHSTP Formative Research and Tool Development (OMB Control Number 0920-0840, expiration 09/29/2016) is designed to support formative research in HIV/AIDS, sexually transmitted diseases, tuberculosis,, and viral hepatitis. While there may be overlap of specific projects, data collection from NCBDDD projects cannot be accommodated within the burden of the existing generics and will be submitted under this proposed collection. NCBDDD has verified through RegInfo.gov that there are no other federal generic collections that duplicate the study types included in this request.

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

Some surveillance or research activities involve data collection from small business (e.g. medical offices) or small governmental entities; therefore, methods and instrument development activities may also be conducted with these groups. If such activities are conducted, these businesses will be approached in the same manner as the individuals we normally recruit: we will ask the organization to identify the appropriate staff members with whom to conduct the activities. No small businesses should be adversely affected by the formative research being conducted.

A.6. Consequences of Collecting the Information Less Frequently

The information collections will involve a one-time collection of data. There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* **Attachment B**). The notice, as required by 5 CFR 1320.8 (d), was published on March 6, 2013, (volume 78, number 44, pages 14553 - 14554). No public comments were received in response to this notice.

B. No outside agency was consulted for the development of this request. Consultations related to specific projects will be provided in those respective individual request submissions. The following individuals were consulted for the development of this request:

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

The proposed standard is that incentives will not be offered, and will only be employed when the population is considered hard to reach or recruit. Any incentive offered will not exceed the government-wide standard for cognitive testing and focus groups.

A.10. Assurances of Confidentiality Provided to Respondents

Many of the individual data collection activities will require respondents to provide identifying or potentially identifying information to project staff. This information will be removed from any data sent to CDC, and CDC will at no time have access to any data that contains identifiers. Project staff will verify that any IIF that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC.

10.1. Privacy Impact Assessment Information

A. Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.

B. Electronic data will be kept on the project-specific network on a secure server, which is accessible only to users granted rights by the project director and in a secure location with restricted physical access to staff working on the project only.

C. Participation in formative research information collection activities is strictly voluntary. All human subjects regulations will be followed. For some projects, participants may need to provide informed consent **(Attachment D)**. In such cases, respondents will be provided with an informed consent form prior to the start of information collection, and will be allowed to ask questions about the project before deciding whether to participate or not. The consent form will describe the purpose of the study, specifies specific procedures that will be conducted, and protections for the respondent's privacy. Each individual data collection request will provide informed consent forms if required.

D. Some of the individual data collection activities will require respondents to provide identifying or potentially identifying information to project staff. If applicable, persons participating in such projects conducted by NCBDDD will be informed that their data will be maintained in a secure manner and that the data will only be used for purposes stated in the consent form. Personally identifiable information will be removed from any data sent to CDC, and CDC will at no time have access to any data that contains identifiers. Project staff will verify that any IIF that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC. Only authorized project staff will be allowed to have access to study information (whether identifiable or not) and all information will be kept in a locked cabinet and/or locked office with limited access.

Documentation of data collection activities will be provided with each individual data collection request.

Because methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each individual project as they are developed. Projects that need IRB approval will be submitted with a copy of the approval document.

A.11. Justification for Sensitive Questions

No sensitive questions are anticipated; however, any collection of a sensitive nature will be described in that individual data collection submission.

A.12. Estimates of Annualized Burden Hours and Costs

The estimates of annualized burden hours are based on past experience with recruitment and the administration of similar surveys and focus groups. It is estimated that 26,800 respondents will have to be screened annually to recruit the appropriate number of respondents for this data collection activity. Specific information will be provided with each individual project submission. It is estimated that approximately 8 – 10 individual projects will be processed per year using this mechanism. The estimated annual burden hours for this data collection activity are 16,550. There is no cost to respondents other than their time.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
General public and health care providers	Screener	26,800	1	10/60	4,467
General public and health care providers	Consent Forms	10,000	1	5/60	833
General public and health care providers	Moderator's Guide	10,000	1	1	10,000
General public and health care providers	Surveys	5,000	1	15/60	1,250
Total					**16,550**

The annualized cost burden is show in Table A.12.B. The most recent (May 2010) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website (see http://www.bls.gov/oes/current/oes_nat.htm#00-0000) was used to

estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of respondents. Because it is not known what wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $28.36 per hour was used as an estimate of the average hourly wage for the general public and private providers across the country. The total anticipated annual cost to participants for collections of information for all study types will be $469,358.

Exhibit A.12.B. Annualized Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Total Annual Burden (in hours)	Avg. Hourly Wage	Total Respondent Cost
General public and health care providers	Screener	26,800	4,467	$28.36	$126,684
General public and health care providers	Consent Forms	10,000	833	$28.36	$23,624
General public and health care providers	Moderator's Guide	10,000	10,000	$28.36	$283,600
General public and health care providers	Surveys	5,000	1,250	$28.36	$35,450
Total					**$469,358**

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

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

A.14. Annualized Costs to the Federal Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one CDC project officer (GS-12, 13 or 14 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to the local areas implementing the data collection. Travel may be required to provide this technical assistance. In some cases, a CDC technical assistant's time may also be required. While actual annualized costs will vary dependent on the scope of future submissions, it is

estimated that the annual cost to the Federal Government is $193,500. Detailed costs will be submitted with each individual data collection activity.

Table 14.A: Governmental Costs

		Total ($)
Federal Government Personnel Costs	CDC Project Officer (GS-12/13/14 at 0.5 FTE)	$52,000
	CDC Data Manager/Administrative Staff (GS-9/10, 0.25 FTE)	$16,000
	CDC Travel (8 trips)	$15,000
	Subtotal, Federal Direct Costs	$83,000
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	$110,500
Total Annualized Cost to Government		$193,500

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request, therefore program changes and adjustments do not apply.

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

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases where respondents may have to be approached more than once on the same or a similar topic for follow-up evaluation. No single data collection activity will take longer than 1 year to complete from inception of information collection to the first report of findings. Proposed timelines will be submitted for each individual data collection activity.

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

The OMB Expiration Date will be displayed.

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

There are no exceptions to the certification.