Information Collection Request
New

The Natural History of Spina Bifida in Children Pilot Project

Supporting Statement Part A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

This supporting statement is for a new Information Collection Request (ICR). Spina bifida (SB) is considered one of the most complex birth defects compatible with life (e.g., Bowman, McLone, Grant, Tomita, & Ito, 2001). Although public health initiatives, in addition to other factors, have resulted in fewer children being born with SB, neural tube defects are still ranked as one of the most common potentially disabling conditions in the U.S. (Centers for Disease Control and Prevention (CDC), 2006). Concurrently, advances in medical care and technology have resulted in a greater longevity for people with SB. As the life expectancy of individuals with SB increases, the number of people living with SB in the U.S. will increase, in spite of current prevention efforts.

Even though this birth defect is not fully understood, there is a substantial amount of research into the etiology and prevention of SB. However, research on the overall life experience of people with SB is scarce. To date, there are no U.S. population-based cohort studies or programs addressing the natural history of SB. This is of importance because people with SB often experience condition-

specific difficulties and secondary conditions that detrimentally influence several aspects of their lives. For instance, individuals living with SB are at increased risk of urinary and fecal incontinence (Verhoef et al., 2005), complications with renal function (e.g., Bauer & Joseph, 1990; McDonnell & McCann, 2000; Woodhouse, 2006), certain types of learning difficulties (Vaccha & Adams, 2005; Yeates, Loss, Colvin, & Enile, 2003; Iddon, Morgan, Loveday, Sahakian, & Pickard, 2004; Wiedenbauer & Jansen-Osmann, 2006), obesity (e.g., Mita et al., 1993), pressure sores (e.g., Verhoef, Barf, van Asbeck, Gooskens, & Prevo, 2004) and compromised mobility (e.g., Schoenmakers, Uiterwaal, Gulmans, Gooskens, & Helders, 2005; Johnson, Dudgeon, Kuehn, & Walker, 2007). Moreover, hydrocephalus co-occurs with SB 80-95% of the time (e.g., Burmeister et al., 2005; Vinck, Maassen, Mullaart, & Rotteveel, 2006; Wiedenbauer & Jansen-Osmann, 2006) and most people with SB evidence Chiari II malformations (Vinck et al., 2006).

Public health clearly has a leadership role in terms of continuing prevention efforts of neural tube defects. However, public health and CDC also has an essential role to play for people with SB in many other areas including health promotion, the prevention of secondary conditions, access to preventive health care, and caregiver support. We do not yet know how and when to intervene to prevent the onset of or reduce the number of secondary conditions. Although existing research has addressed certain issues relevant to people with SB much still stands to be learned about the natural course of SB throughout the life span. In the rare cases where SB related information is collected prospectively in the U.S., it frequently relies on small convenience samples, or special clinic samples, which limits generalizability. Acknowledging the lack of SB evidence-based information in general, and of treatments and interventions in particular, officials from several federal agencies (e.g., CDC; Interagency Committee on Disability Research; National Institutes of Health; Agency for Healthcare Research and Quality), SB advocacy organizations, and leading SB and disability experts came together in 2003 and collectively highlighted the need for evidence based practice in SB (Liptak, 2003).

The long-term purpose of this project is to increase knowledge about the natural history of SB by prospectively studying children who were born with this potentially disabling condition. To accomplish this goal we are proposing a pilot project to (1) explore the feasibility of locating and recruiting participants using and comparing different sources of recruitment, (2) test a multi-disciplinary module to collect the data, (3) determine the utility of different methods of retrieving the data and, (4) summarize preliminary cross-sectional descriptive information on the natural history of SB. Several of the areas identified at the 2003 meeting as lacking evidence are directly or indirectly included in this ICR, such as development and learning, urology, mobility, orthopedics, and health.

The purposes of this project are consistent with the national research agenda of the CDC's National SB Program, which aims to find answers to improve the quality of life for children, adolescents, and adults who live with SB. The proposed data collection is authorized by the Birth Defects and Developmental Disabilities Prevention Act of 2003 (PL 108-154, Section 317C) which is an amendment to the Public Health Service Act, to include support for a National SB Program (Attachment A).

Privacy Impact Assessment

(i) *Overview of the Data Collection System*

Project participation can take one of two forms: 1) parent participation in a telephone survey (i.e., telephone survey component) or 2) parent and child participation in an in-person assessment (i.e., in-person component). The paper-and-pencil survey (Attachment AA) was developed specifically for this project and will be administered to parents in both components (over the telephone or in-person). In addition to the survey, parental questionnaires and child assessments are included in the in-person component. Data from children's medical and Early Intervention (EI) records (when applicable) will be collected from all consenting participants. The authorization of records release forms can be found in attachments D and E. The records will be copied at the offices where the child receives medical care or EI. The relevant data will subsequently be abstracted (Attachments F-G). In addition, data on recruitment will be collected (Attachment H).

We have contracted with TKC Integration Services (TKCIS), who in turn have subcontracted with the National Opinion Research Center (NORC) at the University of Chicago to assist with recruitment and the telephone survey component of the data collection. TKICS will not be directly involved with recruitment. TKCIS will, however, hire a person to make copies of the consenting participants' medical and EI records and will thus have access to participant data until the data is delivered to the CDC PI. NORC will have access to recruitment information and telephone survey data. We are collaborating with licensed neuropsychologists at the Department of Neuropsychology, Division of Neurosciences, at the Children's Healthcare of Atlanta at Scottish Rite for the in-person component. The neuropsychologists will be responsible for administering the child assessment battery and providing participant feedback when applicable. The in-person component participants have two options; they can (1) participate in the CDC-sponsored research portion only, or, (2) participate in a more in-depth evaluation. The in-depth evaluation consists of the same assessments as the research portion; however, additional information will be collected from the parent(s) in order for the neuropsychologist to provide the parent with more comprehensive feedback about the child's performance. The in-depth evaluation therefore requires a greater time commitment from the family. The rationale for offering parents the option of a more in-depth evaluation and not just the

research portion rests on the premise that many parents are likely interested in receiving more detailed feedback than what is generally available in a typical research protocol. Only CDC will have access to the data from families who participate in the research portion. CDC and the neuropsychologists will have access to the data from the families who participate in the in-depth evaluation. It is critical for the neuropsychologists to have access to these data in order to provide relevant feedback to the families. Moreover, the principal investigator (PI) Dr. Ann Alriksson-Schmidt and the National SB Program coordinator Ms. Judy Thibadeau will have access to the data. Dr. Alriksson-Schmidt will be in charge of the project databases at the CDC and will be involved in the in-person data collection, records abstraction, and data entry. Ms. Thibadeau will assist with the records abstraction.

In light of the overall aim of the project, data will be maintained at the offices of the Disability and Health Branch at the CDC for up to ten years. NORC will be required to discard all project related data once all data have been transferred to the CDC and NORC's involvement in the project is no longer required. NORC will notify the CDC before the project data are destroyed. For those children who participate in the in-depth evaluation of the in-person component, the information will become part of their patient record at the Department of Neuropsychology, Division of Neurosciences, at the Children's Healthcare of Atlanta at Scottish Rite.

(ii) *Items of Information to be Collected*
For both components, information will be collected on the following topics using the parental survey, child assessment, parental questionnaires, and medical and EI records: Family Demographics and Functioning; Medical Concerns; Child Development and Learning; Physical Activity, Nutrition, and Physical Growth; Mobility and Functioning; and General Health. All data will be entered and stored in two SPSS databases at the PI's office at the CDC. Once recruited, participants will be assigned a unique 8-digit case identification number (case id) and a 3-digit linking number. One database will contain both directly and indirectly identifiable information (names, addresses, gender, race, and date of birth) in addition to the 3-digit linking number. The second database will contain the scores and results from the assessments, questionnaires, survey, and records abstractions as well as the 8-digit case id. The databases will be linked using a crosswalk that links the 8-digit case id number to the 3-digit linking number before data analyses if needed. Both collaborators (the neuropsychologists at the Department of Neuropsychology, Division of Neurosciences, at the Children's Healthcare of Atlanta at Scottish Rite) and contractors (NORC) will collect identifiable information. This is addressed further in section A.10.

(iii) *Identification of Website(s) and Website Content Directed at Children under 13 Years of Age*
No website will be available for this project.

Given the nature of this data collection, a system of records will be created under the Privacy Act (5 U.S.C. 552a). This system of records falls under CDC System of Records Notice 09-20-0136 Epidemiologic Studies and Surveillance of Disease Problems.

2. Purpose of Use of the Information Collection

The lack of information about the natural history of SB can be rectified by collecting multi-disciplinary, multi-state longitudinal data. Availability of information about what challenges and facilitates the successful achievement of developmental milestones will assist with the identification and subsequent development of appropriate and timely prevention or intervention strategies for people living with this complex condition. It will also facilitate the development of general guidelines to improve quality of life for people with SB at different stages of life. This undertaking requires pilot testing of the proposed methods before implementation on a larger, national scale. This pilot project is a first step towards the recruitment and longitudinal follow up of a larger, representative sample of people living with SB.

The data collected in this project will be summarized, evaluated, and applied to guide the development of a larger longitudinal multi-state data collection effort. The PI will lead these efforts in collaboration with other professionals at the CDC's Disability and Health Branch who are involved with the National SB Program in general and the current project in particular. This is primarily a formative research effort and will not provide results that can be generalized to all people living with SB. However, the project findings will inform several important areas. For instance, we will learn about the feasibility of using a birth defects surveillance system to recruit participants (as opposed to using a clinic sample) and which data collection methods yield the most reliable and valid information. In addition, participants will be asked to provide open-ended feedback on the survey. The topics addressed in this research are based on recommendations from experts and on "knowledge gaps" identified in the SB literature. Nevertheless, it is important to incorporate feedback from the actual stakeholders, in this case families with children growing up with SB. Eventually, we plan to collaborate with a number of different states that have active birth defect surveillance programs. The results from this pilot project will be presented and discussed with relevant officials from these state programs.

The negative consequences of not collecting the proposed data can be viewed in two ways. First, not having access to longitudinal, preferably population based, information of the natural history of SB will result in a status quo in terms of how and when to intervene as individuals with SB grow and develop throughout life. A recent report found that children with SB incurred medical care utilization and expenditures that were not only substantially higher than children without disabilities, but also higher than other children with special health care needs (Ouyang, Grosse, Armour, & Waitzman, 2007). Thus, there are likely monetary ramifications in addition to potential unnecessary suffering from not having a

better understanding of the life trajectories of people with SB. Second, not conducting a pilot project prior to the implementation of a project of this magnitude may result in a weaker design and methods, which in turn negatively affect the quality of the data and possibly the cost of the project.

Funding for this project comes from a Congressional allocation to the CDC for the purpose of establishing and funding a National SB Program. The National SB Program, including the activities described here, is supported by the President's FY2009 budget request.

Privacy Impact Assessment Information
(i) Why is the information being collected?
This pilot project will primarily test the project methodology and design. Specifically, the data collection will help explore the feasibility of locating and recruiting participants using and comparing different sources of recruitment and testing a multi-disciplinary data collection module. It will also help us determine the utility of different methods of retrieving the data. Preliminary cross-sectional descriptive information will also be compiled.

(ii) What is the intended use of the information?
The information is being collected to guide the future development of a longitudinal study on the natural history of SB.

(iii) Who will the information be shared with, what data elements will be shared, and for what purpose?
NORC will have access to the recruitment and telephone survey data during the data collection phase. Once the project has been completed and NORC has submitted the data to the CDC, NORC will destroy any project data. The data that are collected during the in-depth evaluation in-person component will become part of the children's medical records at the Children's Healthcare of Atlanta at Scottish Rite and subjected to their internal policies on data security. The data collected will be used by the neuropsychologists to provide participant feedback. The consent form for the in-depth in-person component states that the child's data will become part of the child's medical records at the Children's Healthcare of Atlanta at Scottish Rite (see Attachment I).

(iv) What impact will the proposed collection have on privacy?
Collection of medical information may be considered sensitive. In most cases, SB is a visible condition and the medical information that is to be collected is directly related to SB (e.g., number of shunt revisions, level of lesion, and number of diagnosed urinary tract infections) and may be considered less sensitive than medical information related to other conditions. Safeguards to protect the data are described elsewhere (see A10).

3. Use of Improved Information Technology and Burden Reduction

The data from both data collection components will be collected using paper-and-pencil questionnaires and assessments. The use of automated, electronic, mechanical, or other technological collection techniques will not be used for this pilot project. A decision was made to maximize the number of completed cases included in the pilot project rather than devote resources to the development of a computer-assisted personal or telephone interview (CAPI or CATI) instrument. Project resources will be devoted to recruitment, interviewer hours, record abstractions, and respondent incentives for the approximately 40 pilot cases. In addition, during the pilot project it is likely that respondent feedback and data review activities will identify areas of the questionnaire that should be reworked or reworded. Fine-tuning a computerized instrument for a small number of cases would require more financial resources than allocated to the current effort. The in-person component also involves child assessments. These assessments have been standardized and need to be administered in a certain manner in order to provide valid and reliable data. The assessments included in this project have not been standardized using automated, electronic, mechanical, or other types of technological techniques. Not following the carefully detailed administration procedures would jeopardize the accuracy and usefulness of the data.

Although no technological approaches have been proposed for use, the survey instrument has been designed to ensure minimal burden on respondents. Specifically, the instrument includes “skip instructions” which indicate to the interviewer whether particular questions should be administered to a respondent based on his/her earlier responses. These skip instructions are likely to result in a minimized burden for respondents who will be asked only questions that apply to their particular situation and not all questions contained in the questionnaire. Moreover, we have minimized the number of subtests included in the in-person child assessments to ensure that we only collect the minimum amount of data that are necessary to accomplish the project goals.

4. Efforts to Identify Duplication and Use of Similar Information

In 2003, professionals from federal agencies, SB advocacy groups, and clinicians attended a symposium entitled “Evidence-Based Practice in Spina Bifida: Developing a Research Agenda”. The need for, and lack of, longitudinal data to address some of the many gaps about the natural history of SB were discussed. To address this need for prospective data, the Disability and Health Branch later hired a fellow (i.e., project PI) to plan and launch a pilot project on the natural history of SB. In order to avoid data collection duplication, an extensive literature review has been completed to assess what data are currently available and what data are needed. In addition, all professionals involved with the planning of this pilot project regularly attend national and international SB meetings and are well informed regarding what SB research and other initiatives are underway.

Although there are ongoing SB research efforts, most of these rely on small clinic or convenience based samples and have limited generalizability. To our

knowledge, the only U.S. population based national SB research effort is the National Birth Defects Prevention Study (NBDPS). The focus of the NBDPS is on etiology and prevention of birth defects and thus very different from the focus of the proposed project. Other countries have more proactively followed individuals with SB long-term (e.g., the Netherlands) but because of differences in health care, education, and public policies, generalizability to the U.S. SB population is questionable at best.

5. Impact on Small Businesses or Other Small Entities

One of the project recruitment strategies involves outreach to medical practices. Before recruitment efforts begin, we will identify and contact medical practices in Georgia who specialize in pediatric neurosurgery, orthopedics, and urology, as they are likely to have children with SB as patients. Initial contact with the medical practices will be made with a project information letter (see attachment J). Project staff will call the medical practices one to two weeks after the letter has been mailed to identify the appropriate person to talk to and a time convenient for that person to have a conversation regarding the project. The goal of the conversation is to seek verbal permission to post and display recruitment materials in the waiting rooms. Project material will be mailed to those that permit us to post recruitment materials (see Attachments K and L). In those cases where we are not allowed to post recruitment materials the contact person will be thanked and the phone call will be terminated. This recruitment approach does not require that the staff at the medical practice be directly involved with recruitment. Nevertheless, a minor time commitment will be required from one or more of the professionals at the medical practice to learn about the project prior to making a decision as to whether or not to allow us to post recruitment materials.

As part of the project, data will be abstracted from children's medical and EI records (when applicable). Parents who agree to the abstraction of data from their children's records will be asked to sign two separate consent forms (see attachments D and E). The medical practice/s and/or EI site/s will be informed that one of their patients is participating in a research project and that the patient's parent has signed an authorization form allowing us to make a copy of his/her child's records. An appointment will be scheduled for project staff to copy the relevant records. A copy of the signed authorization form and a copy of the signed HIPAA form (see attachment M) will be given to the medical practice and/or EI site for their reference. Staff at the small businesses will not be asked to complete questionnaires, forms, or to perform any records abstraction. In addition, we do not ask the medical practices or EI sites to collect any special information that would not already be collected as part of their ongoing business efforts. However, in order for the relevant records to be copied, staff at the medical practice and/or EI site will have to make the appropriate records available for copying. This minor time commitment may have an impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

The pilot project design requires that data be collected from each respondent only one time. The pilot project will serve to test recruitment strategies, the usefulness of the recruitment materials, respondents' comprehension of the interview questions, and the feasibility of collecting data via telephone or in-person. Preliminary descriptive statistics will be summarized. The results of the project will be used to inform the design of a future larger prospective effort. Should CDC decide to move forward with such a future project as a result of this pilot project, the frequency of the data collection would be determined at that time. There are no known legal obstacles to reduce the burden.

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

This request complies with the regulation 5 CFR 1320.5, except for one special circumstance (i.e., "The information collection is in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study"). Participants in the pilot project will be drawn from the population based Metropolitan Atlanta Congenital Defects Program (MACDP). In addition, a convenience sample will be included consisting of families seeking medical services at an Atlanta based SB clinic or from pediatric medical practices in Georgia specializing in neurosurgery, urology, or orthopedics. Eligible families will also be recruited via the SB Association of Georgia's local chapter. Consequently, results may not be generalizable to the general population of families with children with SB. Moreover, we do not know how many families in the State of Georgia are eligible and willing to participate. We estimate that approximately 40 families will participate in the project. Such a small sample size will likely not result in enough statistical power to compute inferential statistics. However, the overarching project goal is to use the pilot project results to inform the procedures and methodologies for conducting future, population-based studies of families with children with SB.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on February 5, 2008, vol. 73, No. 24, pp. 6727-28 (see Attachment B). There were/are no public comments.

B. We have contracted with the TKCIS, who have subcontracted with NORC at the University of Chicago to assist with certain aspects of the project development. In 2007, Dr. Kari Carris (telephone: 312-759-4295; email: carris-kari@norc.org) and Ms. Keeshawna Brooks (telephone: 312-325-2529; email: Brooks-Keeshawna@norc.org), both at NORC, reviewed and provided feedback on the project design. They were also instrumental in finalizing the project survey and assisting with the Institutional Review Board protocol development. They are currently (2008) assisting with the preparation of the OMB package.

During the development of the medical records abstraction data form in 2007, we consulted with three physicians with expertise in SB. The physicians reviewed the draft of the medical records abstraction form and provided recommendations on the section that covered their specific area of expertise. Following the review, the form was amended to incorporate their recommendations (see attachment F). All three physicians are members of the SB Association's Professional Advisory Council. Dr. David Joseph (telephone: 205-934-6149; email: David.Joseph@ccc.uab.edu) is a pediatric urologist who practices at the University of Alabama at Birmingham. Dr. Jeffrey Parker Blount (telephone: 205-939-9653; email: Jeffrey.Blount@ccc.uab.edu) is a pediatric neurosurgeon and associate professor who practices at the University of Alabama at Birmingham. Finally, Dr. Lee Segal (telephone: 602-546-0264; email: LSEGAL@psu.edu) is an orthopedic surgeon at Phoenix Children's Hospital.

Dr. Fred Biasini (telephone: 205-934-9465; email: fbiasini@sparks.uab.edu), a clinical/developmental psychologist at the University of Alabama at Birmingham, provided feedback on the EI records form. Dr. Biasini as well as Dr. David Marcus (telephone: 404-785-2849; email: david.marcus@choa.org), a Georgia licensed neuropsychologist at the Department of Neuropsychology at Children's Healthcare of Atlanta at Scottish Rite, have provided input on what child assessments to include in the child in-person component.

Finally, Mr. James Kucik (telephone: 404-498-3806; email: JKucik@cdc.gov), a health scientist at the Birth Defects Branch at the National Center on Birth Defects and Developmental Disabilities/CDC, has provided feedback on recruitment strategies and on using birth defects registries for data collection.

No irresolvable problems occurred during any of the consultations. Project participants will have an opportunity to provide feedback on the project survey during the data collection (see item F30 in attachment AA).

9. Explanation of Any Payment or Gift to Respondents

Each respondent that participates in the telephone component, which is expected to last no more than 45 minutes, will receive $25.00 for completing the interview. Each family that participates in the in-person component, which is expected to last no more than 3 hours (including consent process); will receive $50.00 for completing the parent interview and child assessments. In addition, the in-person component participants will be reimbursed for their travel expenses. The current federal mileage rate will be used to determine the mileage reimbursement.

We carefully considered the amount of the incentives and concluded that $25.00 and $ 50.00 would encourage participation but would not be so great as to be considered an inappropriate influence. Certain factors contributed to the proposed incentive structure. Families with a child born with SB constitute a rare, important, and understudied population. Relatively few families have a child born with SB, and consequently, the population of eligible participants is rather small. These families may have additional demands on their time and could potentially

be involved in additional research studies in addition to the proposed pilot project. Yet, the success of this pilot project and the ability to use the results and information gained from it to inform future prospective studies, hinges on the ability to recruit a sufficient number of participants. In addition, we reviewed incentive amounts offered to participants in some recent projects conducted by NORC to inform our proposed incentive structure. For the National Survey of Adoptive Parents, a study of issues facing adoptive parents and their children conducted by NORC and the National Center for Health Statistics/CDC on behalf of the Assistant Secretary for Planning and Evaluation and the Administration for Children and Families, respondents received $25.00 for a 30-40 minute telephone interview. In the Transition to Nicotine Dependence in Adolescence study conducted by NORC on behalf of Columbia University and sponsored by the National Institute on Drug Abuse, parents received $60.00 for a 2-hour in-person interview. For the Study of Women and Personal Protective Equipment for the National Institute for Occupational Safety and Health (NIOSH) et al., respondents received $40.00 for participating in a 45 minute telephone administered cognitive interview or a one hour focus group. For the National Social Life, Health & Aging Project, a study of sexual behavior funded by the National Institutes of Health, cognitive interview respondents received $75.00 for completing an interview and collection of bio-markers in their home, totaling about 2 ½ hours.

The project incentives were reviewed and approved by the CDC Institutional Review Board (IRB; see attachment N). IRB approvals from NORC and the Department of Neuropsychology at Children's Healthcare of Atlanta at Scottish Rite are pending.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. This submission has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0136 entitled: "Epidemiologic Studies and Surveillance of Disease Problems".

B. Personal identifiers such as participants' names, addresses, and telephone numbers will be collected during participant recruitment activities and/or data collection to facilitate the scheduling of interviews, mailing of participant incentives, and mailing written medical and EI authorization forms to parents. We will implement procedures to secure information in identifiable form (IIF) and limit its linkage to response data. These procedures are described below.

Names, addresses, and telephone numbers will be physically separated from response data and will not appear in response data files used for analyses. Hardcopy documents containing participants' names and addresses will be stored in secure, locked cabinets that are accessible only to authorized project staff. During participant recruitment and appointment scheduling activities, NORC

will maintain an electronic Excel file that lists personal identifiers (i.e., participant's name, address, and telephone number) and this file will be stored on the secure NORC Local Area Network (LAN). Access to the file will be controlled through network rights assigned to approved project staff.

As participants agree to participate in the study and set interview appointments, NORC will assign a unique 8-digit case id number and a random 3-digit linking number to each participant. The unique 8-digit case id number will appear in response data files that are delinked from personal identifiers. The random 3-digit linking number will not bear any resemblance to the case id number and it will not appear on response data files. Instead, the 3-digit linking number will appear on the Excel file containing personal identifiers and it will be used to link the personal identifiers to response data via a separately maintained crosswalk. NORC will maintain a separate, secure crosswalk that can be used to match the randomly assigned 3-digit linking number listed in the personal identifier file to the 8-digit case id number in the final response data file. This crosswalk will contain only the randomly assigned 3-digit linking number and the cooresponding case id number from the final data file and will be stored on the secure NORC LAN. NORC will maintain the crosswalk and the Excel file containting personal identifiers until the completion of the project, at which time they will be removed from NORC's LAN and destroyed.

Because NORC is conducting all participant recruitment – including recruitment for the in-person component which will occur in Atlanta, GA under the direction of the PI – we will establish a protocol by which NORC communicates appointments and respondent names and telephone information to the PI to facilitate in-person data collection activities. NORC will transmit the Excel file containing personal identifiers to the CDC PI via a secure File Transfer Protocol (FTP) site or password protected CD-Rom. To communicate in-person appointments, NORC will create a secure shared calendar whereby the PI in Atlanta can view scheduled participant appointments. The calendar will contain the 3-digit linking number and the names of the parent and the child that have been scheduled. When an appointment has been scheduled, the PI will confirm the appointment with the neuropscychology clinic at the Children's Hospital of Atlanta at Scottish Rite in order to prepare appropriately for the upcoming assessment. The PI will then access the crosswalk, which will also be transmitted via a secure FTP site or password-protected CD-Rom, to determine which 8-digit case id number should be assigned to the in-person participants.

NORC will mail the medical and EI records authorization forms to parents who complete the telephone survey component (in-person component participants will be asked to sign these during the assessment). These authorization forms will contain the random 3-digit linking number associated with the personal identifiers; they will not contain the 8-digit case id number found in the final response data files. Parents will be instructed to return the completed authorization forms (which will contain the child's and parents names) directly to the PI at the CDC using a self-addressed stamped envelope provided by the

project. NORC will provide the PI with the crosswalk (on a password protected CD-Rom or via a secure FTP site) so that she can merge the data from the records abstraction exercise with the interview data.

All hardcopy documents containing personal identifiers will be destroyed at the completion of data collection. Respondents may also choose to provide a minimal amount of identifying information, such as only their initials. No identifying data will be included in the final response data files delivered to CDC; instead the IIF will be stored in a separate password protected data file that can only be linked to the response data via access to the separately maintained crosswalk. The following procedures will be used to maintain the privacy of the data:

1) All identifying data will be separated from interview data and kept in secured, locked areas at the data collector's site and CDC office;
2) Data files will be encrypted or password-protected;
3) Personal identifiers will be physically separated from all interview data; and stored in an encrypted or password-protected file that does not contain the 8-digit case id number.

Data collection staff will be trained in protecting confidentiality of respondents and must receive certification of this training prior to collecting data or working with identifying respondent data. In light of the fact that this pilot project could potentially lead to a longitudinal study of children with SB, CDC will maintain the personally identifying information and the ability to link the identifiers to response data for 10 years. Access to this information would facilitate any future attempts to recontact the pilot project participants.

The following indirect or direct personal identifiers will be collected during recruitment and/or data collection activities: parent's name, parent's telephone number, parent's address, parent's employment status, child's name, child's date of birth, child's gender, child's race/ethnicity, and child's medical/EI records. Parents' names, telephone numbers, and mailing addresses will be used to request participation in the project and schedule appointments for the in-person and telephone components; to obtain written parental authorization to abstract the child's medical and EI records (the authorization forms will be mailed to telephone survey component participants); and to mail incentives to telephone survey component participants. Data security measures are described in 10B below.

In light of the project methods, four involved entities will have access to some or all of the project data: (1) CDC, (2) NORC, (3) the neuropsychologists at the Children's Healthcare of Atlanta at Scottish Rite and, (4) a TKCIS contractor. The CDC will own and have access to all data that are collected during the project. NORC will have access to recruitment data for all participants as well as the data collected during the telephone survey component. Once the project is completed and the data have been transferred to the CDC, NORC will destroy hard copies

and computer data files related to the project. The neuropsychologists at the Children's Healthcare of Atlanta will perform the child assessments for the in-person component. If the families choose to participate in the "research-only" portion of the in-person component all the data collected will belong to the CDC only. The neuropsychologists will not keep any records of these assessments. Data will be shared between the CDC and the Children's Healthcare of Atlanta at Scottish Rite for those families who participate in the "in-depth" portion of the in-person component. The consent form for the in-depth portion of the in-person component explicitly states this. The neuropsychologists will use the project data to provide feedback and for clinical care (if desired by the families). TKCIS will hire a contractor who will make copies of the consenting participants medical and EI records. The copies will be delivered to the CDC PI and the TKCIS contractor will not keep any copies of the records.

The original CDC IRB submission for this project has been approved (CDC IRB # 5339). However, because of some necessary changes to the protocol we will submit amendments to the CDC IRB. These changes are reflected in the current ICR. We also have IRB approval from NORC. Once the CDC IRB has reviewed and approved the amendments, we will seek IRB approval from the Children's Healthcare of Atlanta at Scottish Rite. We will not initiate project recruitment or data collection until the appropriate IRB and OMB approvals have been obtained.

Planned Technical, Physical, and Administrative Controls to Minimize Unauthorized Access, Use or Dissemination of the IIF

NORC manages a sophisticated variety of technical, physical, and administrative security controls designed to ensure that access to confidential data is restricted to only those employees that possess both the need and the proper authorization to review such information. These controls will be in place for the data NORC collects during the conduct of this pilot project.

All NORC facilities are physically controlled by keycard, key access and/or a human monitoring system to restrict access to authorized personnel; sensitive areas such as server rooms and wiring closets are further restricted. NORC also employs a wide range of technical measures to maintain network security, including user ID/password controls, controlled software installation, and encryption technologies. Furthermore, administrative processes are in place to further minimize unauthorized access, use, or dissemination of data. All NORC employees sign a statement of ethics as a condition of employment and pledge to maintain the confidentiality of all collected information. Violation of this pledge is cause for termination of employment with NORC. Finally, access to project-specific areas of NORC's LAN is controlled through network access rights. Once a user logs into NORC's LAN, only approved project staff members have access to the project's files.

The in-person component data will be collected at the Children's Healthcare of Atlanta at Scottish Rite. At the end of the assessment, all hard copies of the

participant data forms will be collected by the PI, or other project personnel, and transported to the PI's office at the CDC for data entry and storage. The data of those families participating in the in-depth portion will be scanned into an electronic record to become part of the child's medical records at Children's Healthcare of Atlanta. In order to access the building where the PI's locked office is located at the CDC proper authorization needs to be provided the security guard prior to entry. The PI's personal computer is user ID and password protected. Project data will be encrypted and stored on a secure network. The hard copies of the data will be kept in locked cabinets.

C. The two separate project consent forms for the in-person component are attached in attachments I and O. Verbal consent will be used in the telephone survey component and the interviewer's script consent can be found in attachment AA as part of the survey. Both consent processes (in person and verbal) address how the data will be used. In addition, the consent form for the in-depth portion of the in-person component addresses that the data will be shared with the neuropsychologists at the Healthcare of Atlanta at Scottish Rite. There are also two separate consent forms authorizing the release of the child's medical and EI information (attachments D and E).

D. The voluntary nature of participants' responses and the intended use of the data are included in the two consent forms for the in-person component as well as in the oral script consent (attachments AA, I and O). The voluntary nature of participating in the project is also addressed in the recruitment material (attachments K and L). The sharing of data between the CDC and the neuropsychologists only apply in the "in-depth" in person component. This is addressed in the consent form (attachment I).

11. Justification for Sensitive Questions

This data collection effort does not involve information on criminal behavior, sexual behavior or attitudes, alcohol or drug use, religious beliefs, or social security numbers. The survey instrument does contain items related to race/ethnicity, which some respondents might consider sensitive. Race/ethnicity information is of importance in this project because there are well-established differences in prevalence of SB among different racial and ethnic groups. The natural history of SB may also be related to race/ethnicity. Respondents are told in the informed consent statements that they may choose not to answer any question they do not wish to answer, which includes questions about race and ethnicity. Although medical and EI information will be collected from the children's medical and EI records, this data collection is unlikely to negatively affect the children's future chances of becoming employed given their young age, in addition to the fact that SB in the majority of cases is a visible condition. Medical and EI information is being sought to determine the utility of retrieving data through these types of records. Parents will sign separate authorization forms to release their child's medical and EI records.

12. Estimates of Annualized Burden Hours and Costs

Tables 1, 1a, and 2 provide the ”Estimate of Annualized Burden Hours (Condensed Table)”, “Estimated Annualized Burden Hours (Expanded Table)” and the “Estimated Annualized Burden Costs” for this effort. Project participants will participate in data collection one time only.

Parent participants will choose to complete either the telephone survey (parent only) or in-person component (parent and child). Because one objective of the current pilot project is to determine which component parents prefer to complete, exactly how many participants will complete each component is unknown. For the purposes of estimating the annualized burden hours and costs, we have assumed an equal number of parents (n = 20) will choose to complete each component. Parents who select the in-person component will participate with their 3-, 4-, or 5-year-old child. Furthermore, we are estimating that of the 20 parents participating in the in-person component, 5 parents will participate in the “research-only” and the remaining 15 parents will participate in the “in-depth” evaluation. The child assessments for the “research-only” and the “in-depth” evaluations are identical. Tables 1a and 2 reflect these assumptions. Consequently, we have estimated that approximately 40 parents and 20 children will enroll in the project for a total of 60 participants. In addition, we will solicit the assistance of the SB clinic’s coordinator to identify eligible patients and mail their parents a letter about the project. We anticipate these activities to last no more than 2hrs in total. All 3 tables include the 2 hrs time commitment from the SB clinic coordinator.

In Table 1a, we present estimated annualized burden hours for parent and child (ages 3-, 4-, or 5-years of age) participants in the telephone survey and in-person components as well as the estimated annualized burden hours for the SB clinic coordinator. Table 2 contains estimated annualized burden costs for the parent participants and SB clinic coordinator only. We do not present estimated burden costs associated with the children’s burden hours in Table 2 because no hourly wage exists for children of such a young age. Please note that the children and the parents who participate in the in-person component will be interviewed/assessed simultaneously.

The annualized burden hour estimates presented in Table 1a were determined using one of three means. The average burden per response for the survey form was determined based on the data collection contractor’s prior experience with similar data collection instruments. The average burden per response for the remaining forms was based either on time estimates provided by the publishers of the various assessments or by estimates provided by clinical neuropsychologists experienced in administering the particular measures included in the project. No formal pretests of the forms were conducted.

Table 1. Estimate of Annualized Burden Hours (Condensed Table)

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in	Total burden hours

			hours)	
Parents (phone survey)	20	1	45/60	15
Parents (in-person assessment)	20	1	2.5	50
Child (in-person assessment)	20	1	1.5	30
SB Clinic Coordinator (recruitment effort)	1	1	2.0	2
Total				97

Table 1a. Estimated Annualized Burden Hours (Expanded Table)

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hrs)	Total Burden Hours
Telephone Survey Component					
Parent	AA. Telephone Survey	20	1	45/60	15
Subtotal for Telephone Survey Component: Parent					**15**
In-Person Component					
Parent	AA. Survey	20	1	45/60	15
	AB. McMaster Family Assessment Device	20	1	15/60	5
	AC. Pediatric Evaluation of Disability Inventory	20	1	45/60	15
	AD. Behavior Rating Inventory of Executive Function, Preschool Version	20	1	12/60	4
	AE. Behavior Assessment System for Children, 2nd Edition *(included in in-depth evaluation only)*	15	1	12/60	3
	AF. Adaptive Behavior Assessment System-2nd Edition *(included in in-depth evaluation only)*	15	1	20/60	5
	AG. Children's Healthcare of Atlanta Patient History Questionnaire *(included in in-depth evaluation only)*	15	1	12/60	3
Subtotal for In-Person Component: Parent					**50**
In-Person Component					

Child	AH. Differential Abilities Scale, 2nd Edition	20	1	30/60	10
	AI. Peabody Picture Vocabulary Test, 4th Edition	20	1	12/60	4
	AJ. NEPSY-II (3 subtests)	20	1	12/60	4
	AK. Wide Range Assessment of Visual Motor Abilities (2 subtests)	20	1	15/60	5
	AL. Bracken Basic Concept Scale – School Readiness Composite	20	1	12/60	4
Subtotal for In-Person Component: Child					***27****
Recruitment Effort					
SB Clinic Coordinator	C. SB Clinic Coordinator Recruitment Effort	1	1	2.0	2
Subtotal for SB Clinic Coordinator (recruitment effort)					***2***

***1.35 hours rounded up to 1.5 for a total of 30 burden hours shown in Table 1.**

There are no direct costs to the respondents themselves. Indirect costs to respondents, however, may be calculated in terms of the costs of their time spent in responding to the telephone survey or interview. We have calculated these costs assuming the mean hourly wages for respondents as specified in Table 2 below. We have also included the cost of the SB clinic coordinator recruitment efforts (estimated 2 hrs). This results in $1,234.14 as the total cost for the respondents' time.

Table 2. Estimated Annualized Burden **Costs**

Type of Respondent	Total Burden Hours	Hourly Wage Rate[a]	Total Respondent Costs
Parent – Telephone Survey Component	15	$18.42	$276.30
Parent – In-Person Component	50	$18.42	$921.00
Child – In-Person Component	30	----[b]	----[b]
SB Clinic Coordinator (recruitment time)	2	$18.42	$36.84
Total	**97**		**$1,234.14**

[a] Source: U.S. Department of Labor, Bureau of Labor Statistics Wage Data, Occupational Employment Statistics, May 2007 State Occupational Employment and Wage Estimates, http://www.bls.gov/bls/blswage.htm. Average hourly rate shown is for all occupations in the State of Georgia. http://www.bls.gov/oes/current/oes_ga.htm

[b] We do not present estimated burden costs associated with the children's burden hours because no hourly wage exists for children of such a young age. We have included the children's burden hours in the table for completeness.

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

Data collection for this study will not result in any additional capital, start-up, maintenance, or purchase costs to respondents or record keepers. Therefore, there is no direct financial burden to respondents other than that discussed in the previous section (A12).

14. Annualized Cost to the Government

The project is funded under Contract No. 200-2007-20753 Task 4. The total contract award to TKC Integration Services, LLC is $219,077.37 over a 2-year period. Thus, the average annualized contract cost is $ 109,538.69. These costs cover the following activities:

- Assistance in designing and planning the pilot project
- Feedback on instrument development
- Recruitment and training of telephone interviewers
- Recruitment of respondents
- Incentives for the participants
- Collection, processing, and cleaning of the telephone survey component data
- Administration, scoring, and feedback of child assessments (in-person component)
- Assistance with obtaining parental consent to retrieve children's medical and EI records, as well as actual retrieval of these records
- Development of a data file and report documentation
- Meetings and reporting

Additional costs will be incurred by the government in personnel costs of staff involved in oversight, study design, in-person component data collection, and data analyses. Vincent Campbell and Sandra Coulberson will be involved, each for approximately .01 percent of their time. Direct costs in CDC staff time will approximate $2,415.00 annually ($ 4,830.00 for the total project). Table 3 summarizes indirect government costs. In addition, a contractor will be involved in the oversight and implementation of this project, 0.10 percent of her time and an Association of University Centers on Disabilities (AUCD) fellow (project PI) will be involved 24 hours per week (0.60 FTE).

Table 3. Estimates of Annualized and Total **Costs to the Federal Government**

Expense Type	Expense Explanation	Average Annual Costs	Total Costs (2-years)
Direct Costs to the Federal Government	Vincent Campbell, GS 15. .01 FTE	$1,305.00	$ 2,610.00
	Sandra Coulberson, 14, .01 FTE	$1,110.00	$ 2,220.00

Subtotal, Direct Costs to the Government		**$ 2415.00**	**$ 4,830.00**
Contractor and Other Expenses	TKC Integration Services, LLC Cost and Fees	$ 11,171.07	$ 22,342.14
	NORC Cost and Fees (subcontractor to TKCIS)	$ 98,367.61	$ 196,735.22
	Ann Alriksson-Schmidt, AUCD Fellow, .60 FTE	$46,233.00	$ 92,466.00
	Judy Thibadeau, Contractor, .10 FTE	$10,000.00	$ 20,000.00
Subtotal, Contracted Services		**$ 165,771.68**	**$ 331,543.36**
TOTAL COST TO THE GOVERNMENT		**$ 168,186.68**	**$ 336,373.36**

Therefore, the average annualized cost to the government will be $ 168,186.68 for a total project cost of $ 336,373.36 for the two-year project period.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Plans for Tabulation. As stated in A1 and A2, the main goals of this pilot project are not to provide generalizable results of children living with SB, but to inform a future project in terms of recruitment strategies and methodology. We will tabulate the recruitment strategies (see Table 4) to learn, for instance, how many people contacted NORC to inquire about the project, how many agreed to participate, and which project component participants chose. We will also categorize and tabulate the reasons for refusal to participate. The qualitative open-ended survey feedback from parents will be summarized, reviewed, and used to guide potential revision of the survey instrument. We plan to summarize the results from both project components using basic descriptive statistics (means and standard deviations for continuous data, frequency and percentages for categorical data). In addition to provide information on this particular sample, these analyses will also inform a potential revision of the survey instrument by assessing, for example, number and pattern of survey items refused, and level of variability in responses. No further statistical analyses are planned at this time as the sample size is likely to be small to support inferential statistics.

Table 4. Summary ***of Recruitment Strategies***

Source of Recruitment	No. of Letters Mailed	No. of Responses Returned	No. Authorizing Contact	No. Inquired about Project	No. Agreed to Participate	No. In-Person Component	No. Telephone Survey Component

MACDP	X	X	X	X	X	X	X
SB Clinic	X	NA	N/A	X	X	X	X
Other Pediatric Specialist Clinic	N/A	NA	N/A	X	X	X	X
Spina Bifida Association of Georgia's Website and NBDPS Newsletter	N/A	NA	N/A	X	X	X	X

NA- Not applicable

Plans for Publication. NORC will prepare and submit a final methodology report to the Disability and Health Branch following the completion of the project. Staff from the Disability and Health Branch anticipate to use the project findings internally when preparing for a larger prospective project, and share the pilot project findings with other CDC staff (as appropriate) and with representatives from states that may be interested in a collaborative effort with the CDC to collect prospective data on the natural history of SB.

Highlights from the final project summary report may be shared during professional meetings. We may also publish the findings in an appropriate peer-reviewed journal, as the information gained during this process can be informative to others in the public health or other related field.

Project Time Schedule. The project time schedule is described in Table 5. We plan to complete the project within 20 months after OMB approval.

Table 5. Project Time Schedule

Activity	Time Schedule
Develop Training Materials for Recruitment and Telephone Component; Training for Recruitment and Telephone Component; Training for In-Person Component	1 month after OMB approval
Participant Recruitment (i.e., letters sent to eligible families identified in the MACDP, posting of recruitment material in clinics and medical offices, recruitment posting on SB Association of Georgia's website)	1-4 months after OMB approval
Complete Phone and In-person Components	1-10 months after OMB approval

Retrieve Medical and EI Records	1-11 months after OMB approval
Data Editing, Cleaning, and Submission of Complete Telephone Component Data from NORC to CDC	10-12 months after OMB approval
Methodology Report Writing (NORC Submission of Final Report to CDC)	13 months after OMB approval
Preparation and Presentation of Project Results (including preliminary data analyses)	13-20 months after OMB approval

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

This request will display the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act, apart from exceptions i (i.e., “It uses effective and efficient statistical survey methodology”) and j (i.e., “It makes appropriate use of information technology”). Rationale is provided below as to why these exceptions apply to the pilot project.

(i) The proposed pilot project relies on a convenience sample and a sample drawn from a public health surveillance system. Because the population of children born with SB in Georgia is unknown, it is not possible to draw a representative sample of children from the population at this time. One aim of the proposed study is to determine whether a sampling frame might be created from various different resources such as surveillance systems and clinic or physician records.

(j) Because this is a pilot project that aims to evaluate the data collection instrument and because a relatively small number or participants will be recruited, the data collection instrument will not be programmed into a computer-assisted interview. Interviewers will record respondents’ answers using a hardcopy version of the data collection instrument. However, care has been taken to create a data collection instrument that incorporates skipping patterns so that respondents are asked only questions that are relevant to them, thereby reducing respondent burden.

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