

ATTACHMENT C

Privacy Act Statement

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The Natural History of Spina Bifida: Pilot Project

Question 1: Does the data collection involve collecting sensitive and/or personally identifiable information?

Answer 1: Yes. For parents who agree to participate, complete copies of each child's medical record and early intervention history will be made and kept at the CDC. These medical records will contain the child and parent name, address, phone, and other identifying information.

Portions of these medical records will also be redacted and placed on a data collection form. Data from this form will also be entered into an electronic record system for electronic data analysis. The redacted information will contain medical information about the child's health that may be considered sensitive, but the redacted data will not contain identifying information; instead, a study number which is linked to the patient's identifying information will be recorded on the form and in the electronic data system.

The participants who agree to participate by phone will complete a 201-item survey which will contain some personal and identifying information. The survey addresses the following six domains: medical concerns; development and learning; nutrition and physical growth; mobility and functioning; general health; and family demographics. Although most of the items were created for this specific project, many of the more generic items have previously been used in large national surveys such as the Youth Risk Behavior Survey and the National Early Intervention Longitudinal Study.

The participants who complete the in-person assessment will have a number of standardized tests administered to their child (see protocol for more detailed information).

Question 2: Describe how personal information will be maintained (i.e., locked file cabinet, on computer, etc.) and who will have access to it (employees only, contractors, etc.)

Answer 2: Medical and early intervention records will be accessed after obtaining parental consent. If the parent completes the phone survey component, he/she will be mailed hardcopy forms to authorize the release of the child's medical and early intervention records. The parent will be asked to read, sign and return the forms in a stamped envelope provided by the project. If the parent completes the in-person component, written authorization to release the child's medical and early intervention records will be obtained at the conclusion of the

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in-person session. Copies will be made of the medical records and/or the early intervention records at the respective clinics and sites and taken to the CDC. In addition to receiving a copy of the signed authorization of records release forms, clinics or physician office/s will be given a Documentation Notice for HIPAA Accounting Form to keep in the patient's records.

The telephone survey contains instructions to the NORC interviewer as well as standardized instructions to provide to the project participants. Interviewers will read all questions verbatim and in the order indicated in the questionnaire. The participant's responses will be marked directly on the individual paper-and-pencil (PAPI) copy of the survey. Contact information such as name, address, and telephone numbers will be collected on the final page of the PAPI and used for mailing participants their incentive payment. The PAPI will be formatted in such a way that the final page of the PAPI contains only the contact information so that it can be physically separated from the interview data.

For persons who complete the phone survey, the interviewer will store the completed PAPI form in a secure, locked cabinet following administration of the phone survey. NORC project staff will enter the survey data into an electronic SPSS data file that will be stored on the secure NORC network. The electronic data file will be accessible only to the staff assigned to work on this project. The data entry will be verified by comparing the variable values entered into the data file to those indicated on the PAPI. At the conclusion of the project, the hardcopy PAPI will be shredded.

Identifying information that is collected during the course of the phone interview (e.g., name, addresses, and telephone numbers) will be physically and permanently separated from the interview data and entered into a separate database. This database will be stored on the secure NORC network and accessible only to approved project staff. The database will be used for the purposes of mailing respondent incentives to participants.

For participants who complete the in-person assessment, participants will have binders where the signed consent forms and the hard copies of the data will be kept. The project coordinator will be responsible for taking the binders to her CDC office where the binders will be locked in a file cabinet.

Question 3: How long will the personal information be maintained?

Answer 3: The investigators wish to maintain the complete database with identifying information for up to a ten year period.

Question 4: If identifiable information will be filed and retrieved by the name of the individual. Specify in the cover letter where the consent/advisement language can be found (i.e., The consent form is located in Attachment 2. **or** The

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advisement information is contained in the letter to respondents located in Attachment 4. or The advisement information is contained in the telephone transcript located in Attachment 3.)

Answer 4: The information below is in the in-person consent form (attachment I):
“Federal law says that all personal information we get about you will be kept private and your identity will not be shared with anyone. We are required by federal law to develop and follow strict procedures to protect your information and use your answers only for statistical research. We will not share your name or other information about you with other people. The information we collect will be kept in locked file cabinets and will be available only to the researchers. The tests results that become part of your child’s medical record are also protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)”.

The information below is in the telephone script for the persons who participate by telephone (attachment AA):

“We are designing a project to learn more about what it is like to grow up with spina bifida. The information we collect today will help us design the project and help us identify the best ways to collect information from families like yours. We will ask you questions about your child’s development and learning, mobility and functioning, general health, nutrition and physical growth. There are some questions about possible medical concerns that your child may or may not have experienced. There are also some questions regarding you and your family. When we finish the survey, we will ask you for your consent to review your child’s medical and early intervention records. We will send you two separate forms to authorize the release of the medical and early intervention records. If you would rather not let the project team review your child’s records, that is fine. You can still participate in today’s survey.

Before we continue, I'd like you to know that taking part in this research is voluntary. You may choose not to answer any questions you don't wish to answer, or end the interview at anytime without penalty. Your responses will be kept confidential to the extent allowed by law. In appreciation for your time, we will send you \$25.00. The survey will take about 30-40 minutes.

May I begin the interview?

(Interviewer: Circle one response) YES NO”

The Information below is in both the medical records and early intervention records request and authorization of release forms (attachments D and E): *“The health care providers that you list on the attached sheet are required by law to protect your child’s health information. By signing this document, you authorize these health care providers to release your child’s health information for this research. Those persons who receive your child’s health information are not covered by the Federal HIPAA Privacy Rule. However, they will not release or share your child’s information with anyone”.*