

ATTACHMENT I

In-person Component for Research and Evaluation Consent Form

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Flesch-Kinkaid Grade Level: 8.1

The Natural History of Spina Bifida in Children Pilot Project

Consent to be in The Natural History of Spina Bifida in Children Pilot Project

(In-person Component for Research and Evaluation)

Participant Identification Number: _____

The Disability and Health Branch at the Centers for Disease Control and Prevention (CDC) and the National Opinion Research Center (NORC) at the University of Chicago invite you and your child to be in a research project about spina bifida. Please ask questions if there is anything you do not understand.

Why are we doing this project? The CDC is designing a project that will help us learn more about what life is like for families who have a young child 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.

How long will you need my child and me? You and your child's participation should last about 3 hours. Each of you can participate at the same time.

What do you want me to do if I decide to be in this study? If you want to be in the study you will be asked questions about your child's medical care, development and learning, general health, mobility and functioning, and nutrition. There will also be a few questions about you and your family. Some of the questionnaires will be for you to fill out on your own. While you are answering these questions, your child will participate in a few tests related to school readiness, development and learning. The results of these tests will be used as data in the research study. The results of the tests will also become part of your child's medical record at the Children's Healthcare of Atlanta at Scottish Rite. The psychologist who gives your child's tests will call you to discuss the results with you. Finally, we will ask if you have any feedback or comments for us about the study.

We will also ask for your consent to contact the clinic/s where your child receives health care to collect information from your child's medical records. In addition, if your child has received or is currently receiving early intervention services we will ask for your consent to collect information from those records as well. This information will help us understand what types of services young children with spina bifida are currently receiving. You will be asked to sign two separate authorization forms for medical and/or early intervention records release. You and your child can still participate in today's study even if you do not allow the project to review your child's records.

Are there any risks to me if I decide to be in this study? There are no known physical risks to you or your child for being in the study. A few questions we will ask you may seem personal or stressful to you. If you or your child would rather not answer a question, just tell us and we will skip it.

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Are there any benefits from being in this study? We hope that you and your child will find the study interesting and will feel that you are contributing to an important project. If you choose to take part in this project, a licensed psychologist will give your child tests that can be used to evaluate your child's development and learning. You will receive feedback from these tests, and the results will become part of your child's medical record at Scottish Rite. You will not have to pay for your child to take these tests.

What alternatives do I have if I don't want to be in your study? It is up to you to decide if you want to be in the study. If you don't want to participate all you need to do is to tell us so. Your and your child's participation is voluntary.

Will there be any costs for participating in the project? There will be no cost to you for participating in this study. You will receive \$50.00 cash to thank you for being in the study.

Will the information I give you be kept private? 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).

Do I have to be in this study? You do not have to be in the study, it is up to you if you want to participate or not. If you do not want to be in the study there will be no loss of benefits to which you are otherwise entitled. If you do decide to be in the study, you are free to stop participation at any time without any penalty.

Who should I call if I have questions about this study or about my rights as a research volunteer? You should contact the project coordinator, Dr. Alriksson-Schmidt, at (404) 498-3487 with any questions you have about the study. If you have questions about your rights as a research volunteer or if you feel that you or your child has been harmed by participating in this research project you may contact CDC's Human Research Protection Office at 1-800-584-8814. You will be asked to leave a message with your contact information. Please refer to protocol #5339, and someone will return your call.

Your cooperation is very important for the success of the study. Thank you very much for your participation.

I have been told about the study. I have been allowed to ask questions. I have had all my questions answered. I would like to participate in the study. By signing this form, I agree to be in the study. I also agree to let my child be in the study. I have been given a copy of this consent form to keep.

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Signature of Parent/Legal guardian
of Child

Date

Signature of Project Representative

Date