CONSENT FORM

Verification of Techniques for Assessing Neurodevelopment in Children

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Introduction

This consent form describes a research study and what you may expect if you decide to allow your child to participate. You are encouraged to read this consent form carefully and to call *your pediatrician or family doctor,* or Dr. Philip Davidson, *the research project director at the University of Rochester* (275-6626) with any questions you may have before making your decision whether or not to allow your child to participate.

Your child is being asked to participate in this project because he or she is a healthy child between 9 and 15 years of age who was hospitalized in the Strong Children's Hospital Neonatal Intensive Care Unit (NICU) and was followed by the Neonatal Continuing Care Program (NCCP).

Purpose of the Study

This study is being conducted to develop a series of tests designed to detect very subtle deficits in thinking, learning, perceiving shapes, sounds and words, problem solving, coordinating movements and performing manual skills. It is known that developmental problems can sometimes be associated with conditions that require hospitalization during infancy and sometimes these problems are very subtle. You may recall the neonatal clinic or tracking program that followed your child during the early years of life to determine if there were early developmental problems. In most cases, these evaluations uncovered no developmental problems and your child has been developing normally. Sometimes, such things as delays in cognitive, motor or language development might have been found. The research is designed to see if the new test battery is able to detect these types of delays among middle school-aged children. After the tests have been developed, they will be used in a research project to determine whether or not the children being studied in that project have subtle changes in their abilities. Children between 9 and 15 years of age have little difficulty performing these tests and that most find them quite enjoyable.

The funding for this research comes from the US Department of Health and Human Services, and several private foundations.

Description of Study Procedures

The test series includes three types of tasks or procedures:

- Tests of thinking, problem solving, and information processing. (These tasks are done either with paper and pencil, by listening to tape recordings and responding verbally or by playing computer games with a touch-screen monitor); Most of these tests are already in wide use for assessing cognitive functions in children, including a standard intelligence test, several tests of auditory processing, and a number of standard neuropsychological tests. Also included are computerized adult learning tasks that we adapted for use with children;
- Tests of sensory ability and manual dexterity. These include tests of quickness and accuracy of movements, picking out dim shapes on a computer screen when presented in a darkened room, picking out letters in the alphabet that flashed on a computer screen, and a computerized test of alertness and coordination (a computer game simulating airplane controls); and
- Non-invasive electrical recordings of brain activity during visual, auditory and motor tasks. For these tasks, your child will wear some wires on his or her head. Specific functions to be tested include auditory brainstem responses, visual evoked potentials, and several tests of hearing.

The testing requires a total of about seven hours. If you prefer, it can be done all in one session in one day or it can be split into two sessions over two days. It will take place at the University of Rochester Medical Center during a day sometime after May 1, 2000. If you consent to have your child participate, Ms. Jean Sloane-Reeves, the project coordinator, will call you to schedule an appointment. You may accompany your child to the testing session and may meet with him or her during the several breaks that are built into the session. You may not sit in with your child during the test sessions themselves. About one week prior to the first scheduled session, you will be sent a reminder letter with directions to the study center.

Your child's appointment will be scheduled in one of two ways, depending on your preference:

1. If you choose to have testing take place in one day, your child's day will beginning between 8:30 and 9:00 in the morning. There will be about ten minutes of rest time between tests when your child will be able to take a restroom break and have crackers and juice if they are thirsty or hungry. A box lunch will be provided for your child between

the morning and afternoon sessions. You will be able to be with your child during this lunch break which will be about 45 minutes long and will begin at about 12:15 PM. Testing will end between 3:45 and 4:00 in the afternoon.

2. If you choose spread the testing over two days, we will schedule a morning session on one day and an afternoon session on another day. The morning session will begin between 8:30 and 9:00 AM and end between 12:15 and 12:30 PM. The afternoon session will begin at 1:00 PM and end between 3:45 and 4:00 PM. As with the full day testing, breaks will be given to your child. Lunch will not be provided for testing that takes place over two days.

Whichever scheduling option you select, it is also possible to arrange a brief introductory visit where you and your child can meet Ms. Reeves and visit the study center.

Should your child become fatigued or decide not to continue at any time during testing, the session will be ended and your child will be free to leave. Testing will be conducted by a team of investigators listed at the top of the Consent Form or by qualified associates of the investigator.

Risks and Benefits of Participation

There are no known risks of participation. The testing session length may make some children tired. However, session duration is shorter than a typical school day. No children expressed fatigue during the field-testing. In fact, most children thought the tests were fun to take.

The results may prove useful to you in planning for your child's future education. A summary of his or her results will be provided upon your request.

Voluntary Participation and Confidentiality

Your child's participation in this study is completely voluntary. You are completely free to choose whether or not to allow your child to participate. We will be unaware of your child's name unless you sign and return the attached Consent Form to us. You or your child are free to withdraw at any time, for whatever reason, without risking loss of present or future care you would otherwise expect to receive. If you wish to withdraw, simply notify any investigator present at the testing session, or call Dr. Davidson. If you do decide to withdraw, any information pertinent to you or your child will be destroyed.

All records associated with your child's test results will be strictly confidential. Results of this study may be reported to funding agencies or

published in scientific journals but no data identifying you or your child will be included.

Costs and Payments

Participation in the study is free. Children recruited will each be given $40.00 in cash for their participation, paid at the conclusion of the testing session. If you choose to split the testing into two days, $20.00 will be paid at the end of the first day, and the remaining $20.00 paid at the conclusion of the second day. Also, at the conclusion of his or her participation in the study, your child will receive a tee shirt and a $25 gift certificate to Media Play. Your parking costs will be covered for each visit.

Contact Persons

For more information concerning this research, please contact:

Philip W. Davidson, Ph.D. (Senior faculty member responsible for the project)
Professor of Pediatrics
Strong Center for Developmental Disabilities
Box 671
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642
716-275-6626 (Please call collect for long distance)

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, New York 14642-8315, Telephone: (716) 506-0005, for long distance you may call toll-free, (877) 449-4441.

Signatures

- Parent or Legal Guardian

I have read the contents of this form, asked questions, and received answers concerning areas I did not understand. I give my consent for my child to participate in this study by signing this form. I understand that a copy of this form will be given to me for my records.

Child's Name_____
Parent or Legal Guardian's
Name (Printed)_____
Parent or Legal Guardian's
Signature_____
Date_____
Daytime Telephone Number _____

- Investigator

I have verbally presented this Consent Form to the volunteer and answered questions completely.

Investigator's Name (Printed)_____
Investigator's Signature_____
Date_____