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Informed Consent Form for Biomedical Research

The Pennsylvania State University

Title of Project: The Development and Dynamics of Cortical

Motion Processing

Principal Investigator:

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1. Purpose of the study:

The purpose of this research is to study how the brain responds to visual information and how brain responses to visual information differ among infants, children, and adults.

2. Procedures to be followed:

We may record images of your child's face on video or digital camera during or after the study. In some cases, we will ask your child to complete a set of simple vision screening tests in which we ask him or her questions about what he or she sees.

If we plan to collect brain activity data, we first will measure the size of your child's head, and then attach a set of detectors to it. The detectors are either small metal cups or sponges connected to wires. They are like a set of antennas that collect the weak electrical signals everyone's brain naturally gives off. The detectors will be connected to a computer that permits us to record your child's brain activity. We will either put on a small number of detectors (3-7) individually, or a special cap that has 128 of them that can be connected all at once. Before we put on the detectors, we may need to clean your child's scalp with a special paste that can irritate the skin slightly. After the detectors are in place, we will ask your child to sit in a special chair and watch a series of images on a computer monitor. If there is room in the chair, and your child needs or wants you to, he or she may sit on your lap while they watch the computer displays. You will be in the testing room at all times. We will record your child's brain activity while she or he watches the computer monitor. The displays take about 10 seconds each, and there will be 10 to 40 displays to watch in total. The displays will consist of black and white stripes that flash on and off or dots that move in different directions; and other similar, simple

black and white visual patterns. We will take short breaks between the displays, and a longer break about half-way through. When we have finished, we will take the detectors off and help you clean your child's head.

If we do not plan to collect brain activity data, we will show your child similar displays, but observe his or her eye movements. These help us determine whether your child can see differences in the displays. If your child is old enough, we may ask them to tell us what they see by pressing buttons on a keyboard or mouse or by asking them to answer yes/no questions or to point toward a pattern.

3. Discomforts and risks:

Your child may experience some mild skin irritation from the skin cleaner, from electrode paste or solution, or from the electrodes themselves. Your child may also experience mild boredom from the displays.

There is a possibility if your child is photosensitive or has an abnormal brain response to light or patterns that he or she could experience a seizure. Scientists estimate that among 5-24 year-olds, 1 person in 4,000 is susceptible to this sort of seizure. The risk is higher for people with epilepsy or with a family history of seizures induced by flashing lights or visual patterns. But, a seizure caused by light or patterns does not increase the chance of subsequent epilepsy. International guidelines have been developed for visual displays in order to reduce the chance of a person developing a seizure following television or video-game play. We follow these guidelines to the extent possible. If your child experiences any blanking out or loss of consciousness, involuntary jerking or twitching, or any other negative symptom during the study, alert us and we will stop immediately.

The risks involved in this study are the same as those experienced in everyday life while watching TV, movies, videos, or riding in a car.

4. Benefits:

The benefits to you include more knowledge about your child's development. The benefits to society include a better understanding of how the visual portions of the brain develop and change.

5. Duration/time of the procedures and study:

A single visit to the lab will take about 1 hour. We may ask you to return for one or more additional visits. The additional visits will take the same amount of time or possibly less.

6. Alternative procedures that could be utilized:

There is no alternative procedure that could be utilized in this study.

7. Statement of confidentiality:

Your child's participation in this research is confidential. To make sure that your child's participation is confidential, your child's data will be identified by a code number, and only the person(s) in charge will have access to the materials that link your child's name to his/her code. Data will be kept on computers that are controlled by a password and are located in a locked laboratory in 120 Chandlee Building.

Data will kept indefinitely in a secure digital library.

Any photographs taken will be stored on a digital camera. Videos will either be recorded directly onto the computer that is collecting brain activity or on videotape. Only approved laboratory staff will have access to the recordings or photographs. Recordings and photographs will be labeled by code number or the date and time of the recording. The computer files and tapes will be marked with a code number or date, and will be stored on a computer in a locked research laboratory room in 120 Chandlee Building.

Recordings and photographs will kept indefinitely in a secure digital library.

An exception to these protections of confidentiality concerns child abuse. Should a researcher witness an episode of abuse or suspect child abuse, the researcher will report to Dr. Rick Gilmore. Please note that investigators are obligated by ethical standards to report to the appropriate agencies any concerns for a child's well being.

The Office of Human Research Protections in the U.S. Department of Health and Human Services, The Penn State University Office for Research Protections, and The Penn State University Institutional Review Board (IRB) may review records related to this project.

8. Right to ask questions:

You can ask questions about this research. Contact Dr. Rick Gilmore at (814) 865-3664 with questions, complaints, or concerns about the research. You can also call this number if you feel this study has harmed you. If you have questions, concerns, or problems about your rights as a research participant, please contact The Pennsylvania State University's Office for Research Protections (ORP) at (814) 865-1775. The ORP cannot answer questions about research procedures. Questions about research procedures can be answered by the research team.

9. Payment for participation.

Your child will receive $10 and a certificate of completion for your child's one-hour participation in this experiment.

10. Voluntary participation:

Your participation in this research as well as that of your child is voluntary. You may stop at any time. You may also refuse to answer any questions.

If you child becomes upset, we will stop the study.

Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would receive otherwise.

12. Injury Clause:

In the unlikely event your child becomes injured as a result of participation in this study, medical care is available but neither financial compensation nor free medical treatment is provided. By signing this document, you are not waiving any rights that you have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators. In the event of an injury, you may contact Dr. Rick Gilmore, the project's principal investigator (814) 865-3664; rogilmore@psu.edu.

13. Abnormal Test Results:

In the event that abnormal test results are obtained, you will be made aware of the results immediately. It would then be recommended that you contact your private medical provider for follow-up.

I give permission for my child, _____, to participate in this research.

My signature below also indicates that I agree to allow my child to participate in this research. I have read this information, and I will receive a copy of this form after it is signed.

Participant Signature:_____

Date:_____

Person Obtaining Consent:_____

Date:_____