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<b>MEDICAL RECORD</b>	<b>MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
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INSTITUTE: National Institute of Mental Health

STUDY NUMBER: 06-M-0065 PRINCIPAL INVESTIGATOR: Audrey Thurm, Ph.D.

STUDY TITLE: Screening Protocol for Studies of the Pediatric and Developmental Neuroscience Branch

Continuing Review Approved by the IRB on 11/10/15

Amendment Approved by the IRB on 10/06/15 (K)

Date Posted to Web: 11/13/15

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Assent for Minors

### **PURPOSE OF THIS STUDY**

We would like to learn more about you in order to help you and your parents decide if you would like to enter a research study here at the National Institutes of Health. In order to learn as much as we can about you, we would like you to come to NIH to meet with us. The purpose of the NIH visits is to determine if you have any medical problems or behavior problems and to see if you are eligible for a study. Also we would like to explain to you what our studies are about so that you can decide if you would like to be in one of our studies.

### **PROCEDURES**

During your visits here, which may require at several visits, we will perform the following things:

1. In private, we will ask you a lot of questions about your behavior and how you feel.
2. We will ask your parent(s) a lot of questions about your behavior.
3. We will ask you to do some paper and pencil tests to measure many abilities.
4. We may do a physical exam (taking your temperature, listening to your heart and lungs like your regular doctor does).
5. We may do a blood test. Blood will be drawn through a needle in your arm. We will draw no more than 6 tablespoons total.
6. We may ask for a urine sample
7. We may ask you to allow us to videotape part of the interview.
8. We may do a test of your brain waves, called an electroencephalogram (EEG). To do the EEG, first we will clean your head a little bit. Then we will put sticky wires on your scalp and cover the wires with a cap. We will need to rub a little gel in the space between the wires and your head, which may scratch a little bit. The EEG may also be done while you sleep in the hospital. One of your parents can stay with you in your room when you have the overnight EEG done. We may also put some sticky pads on your arms or legs during the EEG. We will take the cap, stickers and wires off you when the EEG is done.
9. We may conduct tests for pregnancy and/or drug use. We will provide your parents with results of these tests. If you are unwilling to have these tests conducted, please let us know so we can discuss this with you.
10. We may do genetic testing.

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### **PATIENT IDENTIFICATION**

### **MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

NIH-2514-2 (10-09)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (2)

STUDY NUMBER: 06-M-0065

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**RISKS/DISCOMFORTS**

There are several things that you should know about before you agree to help us out.

1. To take your blood, you will need to have a needle stick. This could hurt a bit, but the doctors will use EMLA cream to numb the area, so that there shouldn't be much discomfort. There is also a chance that you'll get a bruise ("black and blue" mark) or that you might faint ("pass out") during the blood test, but that doesn't happen very often.
2. Some of the questions in the interviews may be embarrassing or otherwise make you uncomfortable.
3. Some of the paper and pencil tests may be boring or hard. You do not have to finish the tests if they're too hard for you.
4. The information that we gather about you will be kept private, except that we must tell your parents if your life is in danger or your behavior is very risky. If you have been abused (hit or touched inappropriately) the law makes us report this to people who can help you.
5. You may miss some school.

**POSSIBLE BENEFITS**

This study will not help you get better. It will help us learn more about problems children have, so that we might be able to help other children in the future.

**RIGHT OF REFUSAL**

You don't have to do every part of this study if you don't want to.

**RIGHT TO WITHDRAW**

You do not have to take part in this study if you don't want to. If you start the study but don't want to continue, you can stop at any time you want. No one will be angry if you stop.

**COMPENSATION**

You will be paid to be in this study.

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I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Signature of Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_