

<b>MEDICAL RECORD</b>	<b>CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Adult Patient or • Parent, for Minor Patient
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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

Consent for Adult Patient

### INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your health professional.

#### **Purpose**

The purpose of this study is to screen for possible participation in research studies at the NIH. This study may include individuals already participating in other NIH studies.

#### **Background**

The Pediatrics and Developmental Neuroscience Branch studies disorders that start in childhood. These include autism spectrum disorders (ASDs), obsessive-compulsive disorder, and other neurodevelopmental disabilities. Some studies use imaging and other kinds of tests. Other studies test new treatments. Data from this study will be used to learn more about these disorders. Participating in this study does not always mean that you will be able to enroll in another study. This screening study does NOT provide treatment.

#### **Study Population**

Up to 5000 people will be enrolled in this study.

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**Inclusion Criteria**

- Subjects (or their legal guardian or DPA) must be able to understand the purpose of the screening process. They must be able to provide written informed consent.
- Subjects must be willing to have an evaluation which may include a psychiatric interview; and medical, neurological, and laboratory examinations.

**Exclusion Criteria**

- Presence of impairing medical or psychiatric illness.
- Lack of appropriate consent

**Procedures**

You will have 1 to 3 clinic visits over the 1 to 2 months. Each visit will take 1 to 4 hours. These time frames do not include breaks. Therefore, the total time at the NIH may be longer than 4 hours.

Some or all of the following tests (described in detail below) will be done with you:

- Interviews and/or questionnaires
- Cognitive and behavioral testing – test of thinking, attention, memory, coordination, concentration, and specific behaviors
- A physical examination
- Blood and urine tests
- Genetic Testing
- Electroencephalography (EEG)
- The particular procedures we would like you to have are checked below.

 Interviews and questionnaires:

Interviews are done with individuals and with caregivers. They will likely take 4 – 5 hours. Some of these interviews can be done by phone. You also may be asked to fill out some questionnaires. Some questionnaires may be mailed to you before your first appointment. You may also be able to fill some out on-line through a secure, confidential website. Some of the questions may be about personal or sensitive issues. You do not have to answer any question you do not want to. If you skip too many questions, we may not be able to tell if you are eligible for other studies.

 Cognitive and behavioral testing:

We will ask you to take tests done with pen-and-paper or computers. These tests help us learn about thinking, memory, attention, and behavior. Some tests include play with toys.

 Physical examination:

You may have a physical examination. This physical exam is for research purposes only. It does not replace any examination from your regular doctors.

The physical examination may include a blood draw, urine sample, an electrocardiogram (ECG), and an EEG. An ECG assesses heart rhythms.

**MEDICAL RECORD****CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

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 **Electroencephalography (EEG):**

During the EEG, the electrical activity of your brain ("brain waves") will be recorded by placing small metal disc electrodes on your scalp with glue. A conductive gel will be placed in the space between the electrodes and your scalp to make sure there is good contact between them. Your brain waves will be recorded while you are lying quietly. This may also be done overnight while you are sleeping. The EEG usually takes 1 to 2 hours. The electrodes will be taken off once the EEG is completed.

 **Blood Drawing:**

Blood samples in this study may be collected to determine your eligibility to participate in other studies. Blood will be drawn through a needle in your arm. We will draw no more than 6 tablespoons (80 cc) of blood.

Test blood may be used for a drug toxicology screen. If you are female, we may do a pregnancy test. For some of the studies we are screening for, individuals who are pregnant may not be able to take part because we do not know if the procedures affect pregnancy or fetal development. If this is the case, you will not be able to participate in that protocol if you are pregnant. You will be told the results of tests that are done in the NIH clinical laboratory.

If it seems likely that you will move on to another study, then we may ask to draw the research samples of blood at the same time we take the clinical samples. This will be done so that you only have to have your blood taken one time. If you decide not to enroll in another study, the samples will not be used for other research and they will be disposed.

 **Genetic Testing:**

If a clinician determines that genetic testing is indicated to rule in or out a particular condition, as part of the blood draw, you will be asked to give (1-2 teaspoons) of blood, saliva, or other sample for genetic research purposes. The genetic material, DNA, will be extracted from the sample and analyzed in order to identify the genes causing the autism in your family and to help us understand how changes in the genes may cause symptoms.

We may take pictures and videotape you. We would use the videotape for research purposes. For example, we may allow another researcher to watch your behavior. We might also use the videotape to train researchers at the NIMH and other places. If you agree to this, we will ask you to sign another form, entitled "Authorization for Public Information Materials Involving Patients."

The study participation ends when the assessment is done and/or it is decided that you are not eligible for other studies. You may enroll in this study again if there is interest in another study. During the study, please do not stop any medication that you are currently taking.

If in the future you become potentially eligible for other research studies at NIH, we would like your permission to share information about you with other researchers. Your permission only allows the researchers to learn information from this screening and to contact you. If you agree to share this information, then you will be contacted by an investigator. That researcher will get your consent before enrolling you in any additional research.

\_\_\_\_\_ I agree to allow information about me to be shared with other investigators in order for them to contact me regarding other studies.

\_\_\_\_\_ I do not give permission for information about me to be shared with any other investigators.

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NIH-2514-2 (10-84)

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**Capacity Assessment**

Some individuals participating in this study will have a brief interview, called a "capacity assessment," with a Clinical Research Advocate from the Human Subjects Protection Unit. The interview will see how well you understand what is involved in participating in this study and whether you might need to have someone else give consent for you to participate. After the interview is complete, the Advocate will talk to you and the research team about the assessment.

**Risks, Inconveniences and Discomforts**

The study described above may involve the following risks:

1. Interview, history and physical examination: Interviews and behavioral testing may be inconvenient because of the time involved. There may be discomfort in talking about the details of how you feel. You may refuse to answer any question you do not wish to answer. You may quit the interview at any time.
2. Cognitive and behavioral testing: The cognitive and behavioral testing you will have is not harmful. They may be frustrating or stressful. We only ask that you try your best. No one performs perfectly on these tasks. You may stop a test at any time and for any reason.
3. There is no risk associated with having an EEG. You may feel uncomfortable while the electrodes are attached to your scalp. The conductive gel sometimes causes some mild irritation. You may not like the smell of the paste or the glue remover, but they are not harmful.
4. Blood draw: You may have some discomfort and bruising at the site of needle entry. We may use EMLA cream a topical anesthetic that can reduce discomfort from the needle stick during blood drawing. There is a very small risk of fainting. Infection in the area of the needle insertion is rare.
5. Genetic Testing: Genetic testing can provide information about how health or illness is passed on within your family. This knowledge may affect your emotional wellbeing. You might feel differently about your life if you learned that you or your children were at increased risk of a disease, especially if there were no treatments. Your children, brothers or sisters may find out that they are at risk for health problems because of information found out about you, which might affect your relationships with them. Other family members may also be affected by uncovering risks they have but did not want to know about. This information can cause stress, anxiety, or depression.

Some genetic testing can also determine if people are directly related. These tests sometimes show that people were adopted or that their biological parent is someone other than their legal parent. If these facts were not known previously, they could be troubling. Genetic counseling is available at the National Institutes of Health to help you understand the nature and implications of you and your family's genetic findings.

Because of the emotional risk, some people who participate in research do not want to know the results of genetic testing. It is our policy to not disclose the results of genetic testing unless it may have direct medical or reproductive implications for you or your family. You may choose to receive your or your minor child's information or you may choose not to receive the information. Whether you choose to receive the information or not, by agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, you can contact the principal investigator of this study.

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Results of genetic testing obtained at NIH are often preliminary and difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified. You may be referred to another laboratory for clinical testing or confirmation.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH. Genetic information about you will not be revealed to others, including your relatives, without your written permission. Similarly, you will not receive information about other family members. You may only receive information about yourself or your minor children. Parents are entitled to copies of their minor child's medical records without consent of the child.

Problems, such as with insurance or employment discrimination, may occur if you disclose information about yourself or agree to have your research records released. We will not release any information about you or your family to any physician, insurance company or employer unless you sign a document allowing release of the information.

**Anticipated Benefits**

You will not directly benefit from participation in this study. However, we hope to learn more about neurodevelopmental disorders from this research study that could help others.

**Right of Withdrawal and Conditions for Early Withdrawal**

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

**Durable Power of Attorney**

You have an illness that may impair your ability to think clearly and make decisions now or in the future. To participate in this study, you may need to appoint a Durable Power of Attorney (DPA) for research and medical care at NIH. The person you appoint will make decisions about your research participation and medical care at NIH only if you become unable to make decisions yourself. The person you choose might be a spouse, relative, or a close friend. It is important that she or he know your preferences about research and medical care. The DPA has no legal standing outside of NIH.

**Discussion of New Findings with You**

We will give you results from tests that are clinically meaningful. We will give results to your health care providers with your written permission. If we find any serious medical or psychiatric condition that needs hospitalization, we will refer you to the appropriate setting for care. Investigators may also provide general information on referrals. They will not initiate referrals to outside services.

**Study Termination**

This study could be terminated if it was decided screening should not happen through this protocol. There would be no negative consequences of terminating the study early.

**Alternatives to Participation or Treatment**

Participation in this screening evaluation is completely voluntary. ***This study does not provide treatment. This study does not replace any therapy that your own doctor is giving you.***

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**Confidentiality**

Your participation in the study will stay confidential. No information that can be identified as coming from you will be shared with others without your written consent, except: 1) if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); 2) if required by law (for example, the Federal Privacy Act allows release of some information from your medical record without your permission if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people). Also, we are required by law to report evidence of abuse or neglect to the appropriate authorities.

**Data Banking and Sharing:**

Data and research test results will be stored on secured servers on the NIH Campus. De-identified data may be submitted to local, national and international data banks and shared with other qualified researchers globally.

Before your data are shared, your name and identifying information will be removed. In some cases we will assign a code to your data. The key to the code will be kept in a separate secure area and only qualified staff will have access to it. Your DNA sample may be used for other research projects, including those not related to language development or autism. Any future research use will require approval by the institutional review committees. .

If you withdraws from this research project before it is complete, any remaining data that can be identified as yours will be discarded. However, data that are shared or submitted to a data bank before you withdraw will not be discarded.

Your data and samples may be used for other research projects, including those not related to neurodevelopmental or behavioral problems, if you agree. Please initial on the line below that reflects your choice:

\_\_\_\_My data and samples may be used for other research projects including those not related to neurodevelopmental or behavioral problems.

\_\_\_\_I do not want my data and samples used for other research projects. Please destroy my samples and data once this project is complete.

**Compensation and Travel costs**

You may be compensated for research-related discomfort and inconveniences in accord with NIH guidelines. If you are unable to finish the study, you will be paid for those parts completed.

\$20 first hour

\$10/hour

Inconvenience units (1): \$10 for blood draw

Total possible compensation: \$30 - \$70 per visit

NIH may provide travel to and from the Clinical Center in Bethesda, Maryland within the United States. Accommodations may also be provided if an overnight stay is necessary.

**Conflict of Interest**

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

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**OTHER PERTINENT INFORMATION**

**1. Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

**2. Policy Regarding Research-Related Injuries.** The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

**3. Payments.** The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

**4. Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Audrey Thurm, Ph.D. at (301) 435-7962, or Susan Swedo, M.D.; Building 10, Room 1C250, Telephone: (301) 435-6644, or, or you may call Paul Grant, M.D. at (301) 435-6651.

You may also call the Clinical Center Patient Representative at (301) 496-2626.

**5. Consent Document.** Please keep a copy of this document in case you want to read it again.

<b>COMPLETE APPROPRIATE ITEM(S) BELOW:</b>			
<p><b>A. Adult Patient's Consent</b> I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p> <p>_____ Signature of Adult Patient/Legal Representative      Date</p> <p>_____ Print Name</p>	<p><b>B. Parent's Permission for Minor Patient.</b> I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p> <p>_____ Signature of Parent(s)/Guardian      Date</p> <p>_____ Print Name</p>		
<p><b>C. Child's Verbal Assent (If Applicable)</b> The information in the above consent was described to my child and my child agrees to participate in the study.</p> <p>_____ Signature of Parent(s)/Guardian      Date      _____ Print Name</p>			
<b>THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM NOVEMBER 10, 2015 THROUGH DECEMBER 01, 2016.</b>			
<p>_____ Signature of Investigator      Date</p> <p>_____ Print Name</p>	<p>_____ Signature of Witness      Date</p> <p>_____ Print Name</p>		

**PATIENT IDENTIFICATION**

**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)**

• Adult Patient or • Parent, for Minor Patient  
NIH-2514-1 (7-09)  
P.A.: 09-25-00996  
File in Section 4: Protocol Consent