

<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-0238 PRINCIPAL INVESTIGATOR: Susan Swedo, MD

STUDY TITLE: An Investigation of the Efficacy of Mercury Chelation as a Treatment for Autism Spectrum

Latest IRB Review: Initial Review 6/27/06

Latest Amendment Approved: N/A

Legal Guardian Consent: Mercury Chelation for Autism

### 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 personal physician or other health professional.

#### 1. Why is this research being done?

This study is being done to help us discover whether children with autism will benefit from taking DMSA, (meso-2,3-dimercaptosuccinic acid), an oral chelating agent that removes mercury and other metals from the body. Although DMSA is commonly used in the community, it has never been subjected to a controlled study in autism, and there is no proof that it actually helps children with autism. In fact, many pediatricians have warned parents that chelation should not be used for autism, because there is no evidence that mercury causes autism, nor that it contributes to the symptoms of autism. At present, support for the use of chelation in autism is provided by single-case reports of benefits of chelation with DMSA. However, those reports could have been biased in favor of DMSA because of the parents' hopes for the treatment, or DMSA could have received credit for changes that were unrelated to the chelating agent. Thus, a placebo-controlled trial is required to determine whether or not the DMSA is responsible for the reported benefits. A placebo is an inactive compound (fake medicine or sugar pill) that can't possibly help the child's symptoms. Assigning one-half of the children to placebo and the other one-half to DMSA allows doctors to compare and contrast the two compounds. If the

PATIENT IDENTIFICATION

#### CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (4-97)

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File in Section 4: Protocol Consent (1)

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**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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children who receive DMSA do significantly better than those who receive placebo, then it would suggest that DMSA is useful. If the placebo group does as well as those taking DMSA, then there is no reason to prescribe DMSA to children with autism. The study will be useful in either case, as it will help doctors know whether or not to use chelation for autism.

**2. Why are we being invited to participate?**

We want to find out whether DMSA is helpful for children with autism. We believe your child would be a good candidate to participate because (s)he has been diagnosed with an autism spectrum disorder and is still having difficulties with symptoms despite standard treatments; furthermore, you have already completed a screening which has confirmed your child's diagnosis and ruled out any conditions that might be associated with complications during DMSA administration. Those conditions include history of allergic reaction to sulfur or thiol-containing substances, history of previous chelation therapy for autism, history of uncontrolled epilepsy, or presence of a complicating medical condition (such as sickle cell anemia, severe asthma, etc.) If your child has any of those conditions, please tell the study doctor now.

**3. How many people will take part in this research study? What will they do?**

120 children will participate in the study. Because we don't know whether chelation will cause any improvement, we are setting up a trial that has a "placebo-controlled" design. This means that one-half of the children in the trial will get capsules that have DMSA in them while the other half will get "placebo" capsules that look identical, but have no actual DMSA in them. Only the pharmacist who makes the capsules will know whether your child is receiving the real DMSA or the placebo. The capsules will look the same, so that you, your child, and the NIMH doctors won't be able to tell whether the capsules contain chelation agent or placebo. Because the assignment is random, there is a 50:50 chance that your child will receive placebo.

**4. How long will our child take part in this research study?**

The study is just over one-year long. Your child will begin with a baseline evaluation and then receive vitamin supplements for a month before beginning the 12-week long drug study. Your child will be seen in the NIH outpatient clinic one time each month during this period, including a visit at the end of the three months-long drug study. A final visit will be scheduled nine months later, to check on your child's progress.

**5. What happens after our child finishes the study?**

Following the final check-up, your child will be discharged from the NIMH study. The study doctors will not be able to tell you whether your child received DMSA or placebo until all of the children in his study group have finished the trial. Therefore, you may not know which type of pill your child received for many months after your child's participation in the study. The NIMH will not be supplying any study subjects with DMSA after the study ends, nor will they provide you with recommendations for obtaining DMSA in the community, since there is no scientific evidence that DMSA is helpful to children with autism.

**6. How do we know if our child can participate in this study?**

You and your child have already completed the first two tasks – a telephone interview and a screening interview at the NIMH clinic. From the history that you gave and the results of the screening, the NIMH research team has verified your child's diagnosis of an autism spectrum disorder and determined initial eligibility. It has been determined that there is no reason why your child could not participate. At this point, the decision whether or not to proceed belongs to you and your

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child. The NIMH researchers will go over the study with you in detail, discuss the risks and benefits of the study, and give you an opportunity to ask questions. Then, you will be asked to sign a consent form. If you don't want to proceed, you can leave without signing the forms. If you decide that you want to proceed, you and your child will be asked to complete a thorough set of medical and psychological tests, known as the "baseline evaluation", and begin a month-long multivitamin supplement schedule before possibly starting the study compound.

**7. What procedures, drugs or other treatments are involved in this research study?**

The main purpose of this study is to test the safety and effectiveness of DMSA, a chelating agent. Before starting the study drug, your child will have baseline examination to verify his/her physical health and psychological condition. The baseline evaluation consists of a comprehensive medical history, behavioral/psychological assessment, and physical examination (including laboratory analysis of blood, hair, urine, and stool). The purpose of the comprehensive history, physical examination, and some of the laboratory studies is to make sure that your child is healthy enough to participate in the study. For safety reasons, we also need to make sure that your child has at least detectable levels of mercury or lead in the blood before possibly being exposed to the chelating agent. If any results are found that would keep your child from participating in the study, the NIMH doctors will inform you.

DMSA removes toxic metals such as mercury and lead, but it can also remove beneficial minerals, such as zinc and iron. The purpose of the month-long multivitamin supplement phase is to ensure that your child maintains adequate levels of these essential minerals while receiving the study drug. Your child will continue to take the multivitamin supplement throughout the study period.

After the supplementation month, your child will be randomly assigned to receive a 12 week course of either DMSA or placebo. This 12 week course will be broken up into six 14-day cycles. Your child will take the study compound by mouth three times per day on days 1, 2 and 3 of each 14-day (two weeks) cycle. During the remaining 11 days of the 14-day period, no DMSA/placebo will be administered, but your child will receive the multivitamins supplement.

Clinic visits will be scheduled immediately before and after the 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> cycles. At each check-up, you will answer a set of standardized questions about your child's autism symptoms. There will also be questions about side-effects of the medication, and about your child's physical health. Also, blood, urine, and stool samples will be taken for laboratory testing.

**8. What are the risks and discomforts of this research study?**

We cannot be sure of the risks of DMSA administration in children with autism, because the drug hasn't been tested previously as a treatment for autism. However, DMSA is FDA-approved for treatment of children with lead poisoning, and it is generally considered safe. About 1 in 10 children will experience some side-effects of DMSA, including rashes, upset stomach, vomiting, and diarrhea. In placebo-controlled trials, the rates of these side-effects were no higher than for children receiving placebo (sugar pill), so it is possible that these side-effects were just a normal part of childhood. However, more serious side-effects are possible, such as changes in blood tests that measure how well the child's liver is working, a decrease in the number of white blood cells (the cells that help fight infection) and decreased numbers of platelets (the cells that help blood clot). To our knowledge, there are no risks associated with taking a daily multi-vitamin supplement as recommended by many pediatricians and primary care providers.

At each clinic visit, the NIH doctors will ask you about any problems that your child is experiencing, and will take a blood test to check for possible side-effects. If you notice any problems between clinic visits, you should call the NIH study doctor, or the NIMH on-call physician. If the NIH doctor does not feel that the problem is related to the study drug then

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you will be instructed to call your primary care provider. If you give us permission we would like to send a letter to that doctor so he or she knows that you are participating in the study and knows a little about it. Also it will give them the contact information for the study doctors in case they ever want to contact us. Should any serious side-effects appear, the study drug will be stopped. Your child may be admitted to the NIH hospital for acute treatment and stabilization, if necessary.

None of the procedures in the baseline and biweekly evaluations are harmful, and only the blood test is uncomfortable. Slight bruising and local pain (during the brief procedure) are the only common side effects of venipuncture (the blood drawing procedure). The venipuncture will be done with the usual sterile precautions, although an infection could still occur at the site. The pain of the needle stick is temporary and subsides quickly when the needle is withdrawn. Local bruising, if it occurs, is present for only a few days. To minimize that discomfort, EMLA cream, a local anesthetic will be applied to the blood-drawing site ahead of time to numb the area. For most children, the cream is able to completely numb the area so that the discomfort is negligible. During or immediately after application of the EMLA cream, the skin at the site may become red, swollen or feel "funny" (numbness is expected, but sometimes tingling sensations can occur.) No discomfort is expected with the psychological or cognitive tasks. The tests will be administered in sessions no longer than 1 1/2 hours. You and your child will be offered breaks frequently, and you will both be monitored to ensure that you and your child are not getting tired.

During study participation it is possible that your child's autism symptoms may worsen to such an extent that you and/or the study physician feel it is in your child's best interest to stop the study early. If this happens, the doctors will work with you and your child's doctor to ensure that he receives optimal care.

**9. Are there any benefits to us if we take part in this research study?**

This study is not designed to benefit your child directly, and it is possible that there will be no benefit to your child from participating in the study. The NIMH doctors do not know if chelation will be helpful. There is a small possibility that taking the study medicine will make your child worse. If that should happen, the study drug would be stopped. At the end of the 12 weeks treatment phase, all medication will be stopped, regardless of whether your child got better or not.

You and your child may also benefit from knowing that you have participated in scientific research which may lead to effective treatments for others who are suffering.

**10. What other choices do we have?**

You do not need to participate in this study to obtain appropriate care for your child. Treatments, such as behavior therapy or medications, are available in the community and may be of benefit to your child. Although it is not advised, you could obtain DMSA without a prescription from health food stores and on-line pharmaceutical suppliers.

**11. Is there a possibility that we might end our participation early?**

At any point during the research, you or your child can choose to discontinue participation in the research. The NIMH doctors reserve this right as well. If your child's symptoms worsen significantly while your child is taking the study drug, or if there are any unforeseen side-effects of the medication, then the drug would be stopped and your child would end the study early. The NIH doctors would provide short-term treatment for the side-effects and then help your child's doctor stabilize his treatment regimen. Your child would still come to the clinic for the scheduled follow-up visits, but (s)he would not take any more study medicine.

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**12. What will happen when the research study is over?**

When the research study is over, the NIMH doctors will analyze the results and write a paper to be published in a medical journal. The paper will be written regardless of whether chelation therapy works or it doesn't. The results of the study will be shared with you and your child at that time (usually by sending you a copy of the paper and an explanation of the results) if you indicate your interest in the results and keep us informed of your mailing address.

**13. Will our clinical reports and test results be shared with us?**

Any laboratory studies that are done by the NIH Clinical Center can be shared with you. Those done by research laboratories cannot be shared with you, because of laboratory certification rules. The results of the baseline evaluation and laboratory studies can also be shared with your child's doctor, if you give us written permission to do so.

**14. Will any of our blood, tissue or other samples be stored and used for research in the future?**

Data and samples collected as part of this study will be stored on the NIH campus or at outside facilities with appropriate security. Samples will be inventoried by code and the key to the code will be kept in a separate, secure area. Access to the code which contains your personal information will be restricted to the principal and associate investigators who are part of this study.

Your child's blood and urine samples will be kept in a freezer until the study ends, so that they can be analyzed at the same time as the other study participants'. The samples will be analyzed at a laboratory supervised by investigators at the National Institute of Environmental Health Sciences (part of NIH). In the future, it is possible that your child's blood samples or research data may be shared with investigators outside of NIH for research on autism and related disorders. If approval is granted for this research, the samples and data will remain coded and will not contain any personal identifiers. The outside researchers will not be given access to the code containing your child's personal information (name, address, medical record number, or social security number) No extra samples will be collected for those research studies.

**15. Will we receive any compensation (money or other) for taking part in this research study?**

You and your child will not receive any compensation for participation in this study. You will receive reimbursement for your travel expenses, including lodging and food for the baseline visit.

**16. Do any of the researchers or the NIH have a financial interest related to this research study?**

The NIH researchers are paid for doing research, including this study, but do not receive any other financial incentives for doing the study. In fact, NIH regulations prohibit them from holding stock in pharmaceutical companies, receiving honoraria from private firms, or otherwise benefiting personally from their research position.

**17. What privacy and confidentiality procedures apply to the information gathered about us in this study?**

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 records. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance. The

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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 records without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

Your child's information will be kept private. However, if, during the course of the study, there is any concern that your child has been abused, we are obligated by law to report it to the appropriate authorities.

**18. What is the NIH's policy regarding research-related injuries?**

The Clinical Center of the NIH 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.

**19. Who can answer our questions about the research and our rights as a research subject?**

You will be given a copy of this consent document in case you want to refer to it or read it again.

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator of this study Susan Swedo, M.D. at 301-496-5323. Her address is National Institute of Mental Health, Building 10, Room 4N208, Bethesda, MD 20892.

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

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**PATIENT IDENTIFICATION****CONTINUATION SHEET for either:**

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NIH-2514-2 (10-84)

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**MEDICAL RECORD****CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

• Adult Patient or • Parent, for Minor Patient

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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 other authorized people.

**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.

**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 Susan Swedo, MD, Building: 10, Room4N208, Telephone: (301) 496-5323.

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.

**COMPLETE APPROPRIATE ITEM(S) BELOW:****A. Adult Patient's Consent**

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.

Signature of Adult Patient/Legal Representative

Date

**B. Parent's Permission for Minor Patient.**

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.)

Signature of Parent(s)/Guardian

Date

**C. Child's Verbal Assent (If Applicable)**

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian

Date

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE  
FROM JUNE 27, 2006 THROUGH JUNE 27, 2007.**

Signature of Investigator

Date

Signature of Witness

Date

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

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (5-98)

P.A.: 09-25-0099

**FAX TO: (301) 480-3126**

File in Section 4: Protocol Consent

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**MEDICAL RECORD****MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**• 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-0238

PRINCIPAL INVESTIGATOR: Susan Swedo, MD

STUDY TITLE: An Investigation of the Efficacy of Mercury Chelation as a Treatment for Autism Spectrum

Latest IRB Review: Initial Review 6/27/06

Latest Amendment Approved: N/A

Minor Patient Assent: Chelation for Autism

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You may have some questions about why you are here and what you are being asked to do. Maybe some of the questions are like these:

Why are you doing this research study?

You are being invited to take part in this study because you have autism, or an autism spectrum disorder. The purpose of this study is to find out if DMSA can help the symptoms of autism. DMSA is a drug that helps to get rid of certain metals in your body, including metals that can be bad for you, like mercury. The NIH doctors don't know whether or not the DMSA will help you, because they don't know if removing mercury is helpful to people with autism. Because it may take a long time to see whether or not the DMSA works, the study will last for about one year.

**What would I have to do if I decided to be part of the study?**

For the first month, you will just take a vitamin pill once each day. This is to make sure that you have the right minerals in your body before we start. You will keep taking the vitamin the whole time. For the next three months, you will take the study pills. This could be either real DMSA or a placebo pill. Placebos are "fake medicine" or sugar pills that don't help you, or hurt you. The placebo pills will look just like the DMSA pills so that you, your parents, and the NIH doctors won't know if you're getting real DMSA or not. This helps the NIH doctors decide if DMSA is really useful for autism, or your symptoms would get better on their own. Because of how DMSA works, you don't have to take these study pills every single day like most medicines. Instead, you will take them three times a day, for three days every two weeks (14 days). The other 11 days you just take your vitamin. We will remind you and your parents which days to take the study pills.

You will come to the clinic for a check-up once every month or so. During those check-ups, you will answer questions about how you're feeling and you will have a blood test. The check-ups will help the NIH doctors find out if you're getting better, and also make sure that you're not having any problems from the study pills (the DMSA or placebo pills). You will have a blood test every time you have a check-up at the NIH. We will use some numbing cream on your arm before the blood test, so that the needle-stick shouldn't be too uncomfortable. If it does hurt, it only lasts for a few seconds. You will also be asked to give us a urine sample (that is, to pee in a cup). This will be done in a private bathroom. We also need you to give us some of your stool (poop). This can be done when you go to the bathroom at home before you come into the clinic. We give you a special container and your parents can bring it in with you.

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

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We will also ask you to help us learn more about your symptoms of autism. You will have to answer a lot of questions and fill out some questionnaires. You will do this three times - before you start the study, when you finish taking the study medicine, and once more when you come back at the end of the study. The questionnaires and interview may become boring; if so, you can skip the boring questions or stop at any time.

**Could the study medicine make me sick?**

You have a 50:50 chance of getting placebo – the sugar pill or fake medicine. The placebo should not make you sick. A small number of children who take DMSA get a rash, an upset stomach or have other problems. If this happens to you, you should tell your parents so that they can let the NIH doctors know. The doctors may decide to stop the study pills until you feel better, or they may lower the dose of medicine. If you get really sick while you're taking the study pills, the NIH doctors will probably stop the study pills and have you finish the study early.

**What if I don't want to do this? What if I change my mind?**

This is a research study, so it is entirely your choice whether or not you do it. If you don't want to be in the study, then you don't have to do it. If you change your mind part way through the study, and decide that you don't want to be in the study, then you can stop at any time. No one will be mad at you. Even your parents could not make you stay in the study if you don't want to, because it has to be what you want to do, not what they want you to do.

If you don't want to take medicine, then you shouldn't be in the study. If you're really scared about blood tests or check-ups, then you might not want to be in the study, because you will have them every time you come to the NIH clinic.

If you have problems with the medicine, or your symptoms get worse during the study, the NIH doctors may decide to stop the study medicine early. If this happens to you, don't worry about it, it won't ruin the study. The NIH doctors may do a few more check-ups after you stop the medicine to make sure that you're doing OK

**How long will the study last?**

The study is scheduled to last for one year. You will take the multivitamin for the first month and then you will take the study medicine for three months. You will have a check-up in the NIH Clinic every month for the first 4 months, and then at the end of the study (one year after you start).

**Will anybody find out that I was in this study?**

The information that we obtain in this study will be kept private. The only people who will know about it are you, your parents, and the research team. If you want us to tell your doctor about the study, we can do that, if you give us written permission. There is one time that the NIH doctors break the privacy rules, and that is if you or a family member tells us information that we think your parents need to know to be able to keep you or other people safe. We are also required by law to report to the authorities any signs that make us concerned that you are being abused.

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

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**What if I have more questions later?**

You may ask any questions you want, anytime. We want you to understand completely what you are agreeing to do.

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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: \_\_\_\_\_

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

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