CONSENT FORM

TITLE OF RESEARCH:	PREVENTING EPILEPSY USING VIGABATRIN IN INFANTS WITH TUBEROUS SCLEROSIS COMPLEX (PREVeNT TRIAL) A randomized, double-blind, placebo-controlled seizure prevention clinical trial for infants with Tuberous Sclerosis Complex (TSC)
IRB PROTOCOL NO.:	IRB-160509001
INVESTIGATOR:	Martina Bebin, MD, MPA
SPONSOR:	National Institute of Neurological Disorders and Stroke (NINDS)
DRUG PROVIDED BY:	Lundbeck Pharmaceuticals

Purpose of the Research

We are asking you to allow your child to take part in a research study. This research study will help learn more about how babies who have Tuberous Sclerosis Complex (TSC) develop infantile spasms or seizures. We want to see if treatment with vigabatrin in infants with TSC can prevent or lower the risk of developing infantile spasms or refractory seizures. Additionally, we will follow closely the development of any side effects during the study that may be related to the administration of the study medication. Vigabatrin was approved by the U.S. Food and Drug Administration (FDA) in 2009 for the treatment of infantile spasms. However, it has not yet been approved as a preventative medication for seizures in patients with Tuberous Sclerosis Complex (TSC). The use of vigabatrin will be considered investigational in this study.

If your child qualifies for the study, he/she will be randomly picked (like the flip of a coin) to receive either vigabatrin or placebo. A placebo does not have any active medicine, so it should not have any effect on your child's TSC. This will be a double-blind study. This means neither you nor your child's doctors will know which medicine your child is taking.

The study doctor will discuss with you the responsibilities as a participant. This study will enroll up to 85 participants at 13 clinical research sites across the United States and 12 of those participants will come from UAB.

Explanation of Procedures

If your child qualifies for the study, you will bring your child to UAB for up to 13 study visits until they are 3 years of age. Your child will have a physical exam by the doctor, video EEGs (monitoring your child's brain waves with small metal discs stuck on the outside of the head and a video camera during the testing to watch your child's movement), eye exams and assessments to look at your child's early learning, motor and language development over the course of the study.

If your child is randomized to blinded treatment Arm A, he or she will receive study drug or placebo until 24 months of age and followed until 36 months of age. If your child has a seizure during the blinded treatment phase of the study, he or she will go on open label vigabatrin, which is Arm B. If your child enrolls in the study because he or she has never had a seizure and a normal EEG, he or she will not be treated but will be followed until 36 months of age.

Your child should not be in this study if he/she:

- Is greater than 6 months of age
- Has not been diagnosed with TSC
- Has a history of seizures or infantile spasms
- Has taken an anti-seizure medication including vigabatrin, or specific oral medication such everolimus or sirolimus (mTOR inhibitor),
- Low carbohydrate and high fat diet, or other anti-seizure medication or anti-seizure therapeutic agent such as cannabidiol.
- Was born prematurely. This is defined as less than 30 weeks at the time of delivery. Exceptions may be made on a case-by-case basis.
- Has taken an investigational drug as part of another research study, within 30 days prior to enrollment or plans on taking an investigational drug and/or participating in an experimental behavioral early intervention study at any time during the duration of the study.

If you agree to allow your child to participate, these are the things that will happen in the study:

- You will watch a seizure educational teaching video and have an opportunity to ask the physician and /or research coordinator questions.
- Medical History / Family History: You will be asked questions about your child's health and your family history.
- Physical Exam: Your child will be checked to see how he/she is doing. This exam will take approximately 30 minutes to complete.

Neuropsychological Evaluations: Assessments, or tests, of how your child is learning and developing. These tests will be performed at your child's baseline (if child enrolls at 6 months of age), 6, 12, 24 and 36 month visit by a psychologist.

- Questionnaires/Interviews: You will answer questions about how your child is growing and learning new things.
- Video EEG (electroencephalogram or brain wave test): An EEG is a test that measures your child's brain's electrical activity. This test helps to see if seizures are occurring and what kind they are. During the EEG, electrodes (small metal discs) are stuck to your child's head with removable paste or glue. The test is painless. At the end, the electrodes and the paste or glue are removed. The video helps find out if certain movements are seizures. The EEG is usually done for children with seizures. The video is being done as part of this study. The EEG will be scheduled based on your child's feeding and napping schedule so that he or she may fall asleep during part of the procedure. The EEG will last about 1 and ½ hours. The EEG will be performed at each of your child's study visits.
- Eye Exam: Your child will have an eye evaluation at baseline, at 4 weeks after medication randomization and defined intervals thereafter, typically every 12 weeks.
- Optional Genetic Testing: If your child has not had clinical genetic testing prior to study enrollment and your insurance does not cover the testing, your child is eligible to have genetic testing done through the study. The initial sample will be sent to Van Andel Institute in Grand Rapids, MI, however, testing will be done at a CLIA-certified laboratory at the University of Alabama at Birmingham. Because the lab is CLIA-certified, we can provide results to you.
- Optional Serum Biomarker Testing: Blood samples for serum biomarkers will be drawn at the time of your child's enrollment and then at three to four additional time points during the 3 year study. The sample will be less than 1 tsp of blood per blood draw. The number of blood draws will be determined based on if your child develops seizures during the study. These samples may be stored for future use.
- To get all the information we need, we may need to get past medical records from other doctors, clinics, or hospitals. You may be asked to sign a separate medical information release form so that medical records can be transferred to UAB. If your child enters and completes the entire study, your child will be in the research study until they reach 3 years of age.

Your child will have EEGs completed at scheduled intervals throughout the study. If at any time the EEG shows changes that indicate your child may be at risk for developing seizures they will be randomly picked (like the flip of a coin) to receive either vigabatrin or placebo. Your child will be dispensed medication at the time of randomization and will either begin vigabatrin or placebo. At each visit you will return any unused study medication and new study medication will be given at your child's visit. If at any time during the study a seizure is witnessed, you should contact the study coordinator to arrange a follow up visit as soon as possible within 24-48 hours. You will be encouraged to video any suspicious seizure-like

activity that will be reviewed by the doctor and study coordinator. An EEG will be completed to confirm the presence of seizures. If it is determined that your child is having seizures, he/she will be transitioned to vigabatrin over a two week period. He/she will be treated based on the type of seizure activity documented. If your child's seizures do not respond to vigabatrin then additional medication options will be recommended per standard of care. Your child will remain in the study and be followed at the outlined scheduled intervals until the age of 36 months. The following schedule shows what happens at each visit.

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	Baseline (Depending on age at enrollment, can be visit 1.5 mo, 3 mo, 4.5 mo, or 6 mo)	~12 wks (3m)	~18 wks (4.5m)	~24 wks (6m)	~30 wks (7.5m)	~36 wks (9m)	~45 wks (10.5m)	~52 wks (12m)	~65 wks (15m)	~78 wks (18m)	~91 wks (21m)	~104 wks (24m)	~156 wks (36m)
Informed consent	✓												
Optional genetic testing	✓												
Optional biomarker blood collection[2]	✓												
Family History & Demographics	✓												
Medical History	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Physical exam	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Video EEG	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Concomitant Medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Eye Exam[1]	✓							✓				✓	✓
Developmental testing[3]	✓			✓				✓				✓	✓

1. Follow up eye exams will continue once the subject has been randomized to either vigabatrin or placebo and as long as the subject is receiving vigabatrin approximately every 12 weeks.
2. Subjects Randomized to vigabatrin or placebo - Biomarker samples will be collected at each subject's enrollment, subject randomization to vigabatrin or placebo, clinical seizures onset, and a final sample after 3 months of seizure control after randomization or 3 months of uncontrolled seizures in the open label phase of the study. Subjects who remain seizure free and have a normal EEG -Biomarker samples will be collected at each subject's enrollment and will have a second biomarker sample collected at 12 months of age and a final sample at 24 months of age.
3. Baseline Developmental testing will occur only if subject enrolls at 6 months of age.

Incidental Findings

Summary scores of your child's developmental testing may not be directly shared with you. However, if results are concerning for developmental delay, you will be informed and have the opportunity to discuss these results further with the investigator.

Risks and Discomforts

Blood draw: Risks associated with a blood draw are pain and bruising. When possible, we will collect blood at the same time that blood is being collected for other reasons. The blood collection volume is within the Children's of Alabama guidelines (Maximum Blood Draw Volumes, version 12/01/14) for blood draws.

Genetic testing: Some people in genetic studies feel nervous about the chance of having a gene that puts them at risk or that may be passed on to their children. If you have these feelings, let us know and we will arrange for you to speak with a genetic counselor.

There might be other risks involved with genetic testing. The testing might find a gene which puts you, your child, or a relative at risk for a genetic disorder in the future. This could affect you and your family if an insurance company or employer find out about the genetic information. We will do our best to keep all information about genetic testing private. Information about genetic testing will only be available to others with your permission.

There is a risk that someone in the future could link your genetic or medical information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. We believe the chance these things will happen is very small, but we cannot guarantee that your identity will never become known. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes.

Vigabatrin: Your child may have some side effects from taking this drug. The side effects of vigabatrin are:

- Sleepiness and fatigue
- Potential abnormal MRI changes in your child's brain: The study doctor will review your child's standard of care MRI of his/her brain before starting this study drug. Your child's treating physician may want to have another standard of care MRI of his/her brain during the use of the study medication.

- Progressive and permanent peripheral vision changes: If vision loss occurs, it will not improve even if the medication is stopped. There is no way to tell if vision loss will develop. Approximately every 12 weeks, eye exams, are required for patients who are taking vigabatrin because of this risk. These tests will not prevent vision loss. However, by stopping the treatment as a result of these tests, the amount of vision loss may be small. As long as vigabatrin is being taken, the risk of vision loss continues. Patients may experience vigabatrin associated visual field loss (VAVFL) which means that a patient's central vision is unaffected and appear clear but they may demonstrate a reduced ability to see things around the edges of their field of vision (peripheral vision). The onset of VAVFL is typically gradual and minor and can occur in 11 to 13% of children based on recent published reports. The likelihood of significant relevant VAVFL is less than 5% and possibly less than 1%. The underlying cause of the VAVFL is thought to be attributed to damage that occurs in the retinal nerve fiber layer of the eye.

Eye Exams: Your child may experience mild discomfort from the eye drops which dilate the pupil of the eye for the examination.

Interviews/Questionnaires: There are a few questionnaires that are quite lengthy and take up some of your time. But we will answer any questions that you may have.

Video EEG: The paste or glue used to apply the electrodes onto your child's scalp may get stuck in your child's hair and require more than one shampooing to remove completely. For a small number of people, the paste or glue can cause mild skin irritation. This normally will heal by itself.

Vigabatrin: Your child may have side effects from taking this drug. The side effects may include sleepiness and drowsy. There may also be abnormal changes in your child's MRI that may show changes in the brain. Your child may experience vision loss. If this occurs, it will not improve even if the medication is stopped. There is no way to tell if vision loss will develop.

Placebo: The placebo does not have any active medicine. A placebo looks like the active study drug but does not contain vigabatrin and therefore does not provide any additional risk to your child.

Randomization: Your child will be assigned to a treatment group by chance, and the treatment your child receives may prove to be less effective or to have more side effects than the other study treatment or other available treatments. If your child is randomized to Arm A, your child may or may not receive study drug and you nor the study doctor will know what treatment your child is assigned to. If your child has a seizure after they are randomized they will move into the "Open Label" phase of the study and receive vigabatrin. Both you and the study doctor will know the dose of vigabatrin your child will receive. If you are randomized to Arm C, your child will not get treatment and will be monitored the same way if the child was given treatment.

Confidentiality: Other potential risks include loss of confidentiality. To protect your child from this risk, all electronic study data will be kept in a password-protected, encrypted database. Other study related materials including video recordings that include personal health information will be kept in a secure area accessible only by study personnel.

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Benefits

Being in this research study may or may not help your child. Children in this research study will be tested to see how they are behaving, growing, and learning new things. If your child shows early signs of a developmental delay, we will refer your child for the proper care so they can receive help sooner than they may have if they weren't in the study. The information learned from this research study may help other children with TSC in the future.

Alternatives

The alternative is to not participate in the study. This will have no effect on the outcome of your child's treatment. Dr. Bebin or study staff will discuss the risks and benefits of alternatives with you.

Confidentiality

Information obtained about your child for this study will be kept confidential to the extent allowed by law. However, research information that identifies your child may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of FDA, NINDS, LUNDBECK Pharmaceuticals, a data coordinating center at UAB, all participating sites that are IRB approved, Van Andel Institute, University of Pennsylvania EEG Portal, and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your child's identity will not be given out.

If any part of this study takes place at Children's of Alabama this consent document will be placed in your child's file at that facility. The document will become part of your child's medical record chart.

Information relating to this study, including your child's name, medical record number, date of birth and social security number, may be shared with the billing offices of Children's of Alabama and its billing agents so that the costs for clinical services can be appropriately paid for by either the study account or by the patient/patient's insurance.

Your child's medical record may indicate that he/she is on a clinical trial and will provide the name and contact information for the principal investigator.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on your genetic information. This law generally will protect your child in the following ways:

- Health insurance companies and group health plans may not request your child's genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect against genetic discrimination by some employers.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify your child, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent your child or a member of your family from voluntarily releasing information about involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

Voluntary Participation and Withdrawal

Whether or not you allow your child to take part in this study is your choice. There will be no penalty if you decide not to allow your child to be in the study. If you decide not to allow your child to be in the study, you will not lose any benefits he/she is otherwise owed. You are free to

withdraw your child from this research study at any time and it will not affect your relationship with this institution. However, your child should return to see the study doctor for safety reasons so he/she can be taken off the study drug and referred for follow-up care.

Your child may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your child's health, or if you are not following the study rules.

Cost of Participation

There will be no cost to you for your child to take part in this study. All drugs, exams and medical care related to this study will be provided to you at no cost during the 3 year study period.

Payment for Participation in Research

There will be no payments for your child's participation in this study. You may be eligible to receive limited reimbursement for travel expenses (such as mileage, taxis, hotel costs, meals, etc.). You will be paid by check and within 30 days of each visit.

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

UAB, Lundbeck Pharmaceuticals and NINDS have not provided for any payment if child is harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your child's doctor or the study staff if new information becomes available that might affect your choice to allow your child to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Martina Bebin. She will be glad to answer any of your questions. Dr. Bebin's number is 205-975-2890 or 256-533-0833.

If you have questions about your child's rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your child's legal rights by signing this informed consent document.

Storage of Specimens for Future Use

Optional Genetic Testing:

Researchers are working to understand TSC and its link to epilepsy and help future patients. If you are agreeable, a blood sample will be taken to collect genetic information on your child. In the event that the original sample collected is not enough or could not be studied, a second sample may be requested. Getting this sample will not benefit your child, but will help us understand the genetics of TSC and help future patients. If blood is already being drawn for another reason, we may ask to have the blood sample for research purposes taken at that time.

Blood samples for future use will be drawn at screening/baseline or at a later visit if preferred by the family. A maximum of 5 ml (1 teaspoon) of blood will be drawn from each child (following guidelines for age/weight and blood draw volumes). Identifiers will be removed from the blood tubes and only the study patient ID will be provided. The de-identified blood samples will be sent to a repository at the TS Alliance. DNA will be extracted from these samples. The DNA samples will be used in genetics studies to identify tuberous sclerosis complex disease phenotype modifiers in future research.

The blood sample will be stored indefinitely for future research. Although researchers will have access to de-identified individual data, any information gained from this research will be reported in anonymous summary form. The samples will be retained indefinitely. Study investigators will maintain and be responsible for deciding how your child's samples and the information obtained from them will be used. All links with your child's identity will be removed from the sample before it is stored or shared. Only de-identified data, which does not include anything that might directly identify your child, will be shared for research purposes. The genetic information may be submitted to the Database of Genotype and Phenotype, an NIH funded resource.

You may request at any time that your child's research samples be removed from storage and not be used for future research. If you decide you want your child's samples removed, you may contact Dr. Bebin at the University of Alabama at Birmingham at 205-975-2890 or 256-533-0833. Once the request is received, and if your child's samples have not been used for other research, they will be destroyed. If you do not make such a request your child's specimens will be stored indefinitely or until used.

Please initial your choice below:

_____ Yes, I grant permission for blood to be collected for genetic testing and used for future research on TSC related disorders.

_____ No, I do not grant permission for blood to be collected for genetic testing and used for future research on TSC related disorders.

and

In the event that the original sample collected is not enough or could not be studied, a second sample may be requested, **please initial your choice below**:

_____ Yes, I grant permission for blood to be collected a second time for genetic testing and used for future research on TSC related disorders.

_____ No, I do not grant permission for blood to be collected a second time for genetic testing and used for future research on TSC related disorders.

Optional Biomarker Specimen Collection:

Additional blood sample will be drawn for future TSC research and will be stored at the TS Alliance Biosample Repository housed at Van Andel Institute in Grand Rapids, MI. The repository is a research resource supported by the National Institute of Health/National Institute of Neurological Disorders and Stroke. The blood samples (less than 1 tsp of blood) will be collected at your child's enrollment visit, then at the visit in which the study drug (either vigabatrin or placebo) is started, and if clinical seizures begin, and a final sample after 3 months of seizure control, or 3 months of uncontrolled seizures.

If your child remains seizure free and has a normal EEG, a second blood sample will be collected at 12 months of age and a final sample at 24 months of age. The proposed future research is to test whether we can detect increase in protein synthesis in white cells in the blood from individuals with TSC.

Data from your child's tests will not be revealed to family members, insurance companies, employers, or other individuals or organizations. Although researchers will have access to de-identified individual data, any information gained from this research will be reported in anonymous summary form. The samples will be retained indefinitely. Study investigators will maintain and be responsible for deciding how your child's samples and the information obtained from them will be used. All links with your child's identity will be removed from the sample before it is stored or shared. Only de-identified data, which does not include anything that might directly identify your child, will be shared for research purposes.

You may request at any time that your child's research samples be removed from storage and not be used for future research. If you decide you want your child's samples removed, you may contact Dr. Bebin at the University of Alabama at Birmingham at 205-975-2890 or 256-533-0833. Once the request is received, and if your child's samples have not been used for other

research, they will be destroyed. If you do not make such a request your child's specimens will be stored indefinitely or until used.

Your child does not have to have blood biomarker samples collection in order to be in this research study.

Please initial your choice below:

_____ Yes, I grant permission for blood to be collected for biomarker testing and used for future research.

_____ No, I do not grant permission for blood to be collected for biomarker testing and used for future research.

and

In the event that the original sample collected is not enough or could not be studied, a second sample may be requested, **please initial your choice below**:

_____ Yes, I grant permission for blood to be collected a second time for biomarker testing and used for future research.

_____ No, I do not grant permission for blood to be collected a second time for biomarker testing and used for future research.

Permission to videotape your child during the developmental assessments:

Brief Observations of Symptoms of Autism (BOSA) will be completed at 24 and 36months. This newly developed instrument based on the format used for the ADOS looks at specific behavioral risk markers for ASD and provides a standardized procedure for detecting each of these markers. The BOSA takes approximately 20 minutes to administer. For the purposes of this study and for future planned analysis, this measure will be videotaped at each site and scored by a PREVeNT psychologist at UAB. UAB will be responsible for centrally storing these videotaped recordings.

- Neuropsychological Evaluations: Assessments, or tests, of cognitive function to test your child's behavior and other skills will be performed at each visit by a psychologist.
    - Autism Assessments (Autism Diagnostic Interview, Autism Observation Scale for Infants, and Autism Diagnostic Observation Schedule) will take up to 3 hours total, with breaks.
    - Developmental Assessments (BOSA, Bayley-III, Preschool Language Scale) will take about 1-1.5 hours total, with breaks.
    - Some of these evaluations may be videotaped and later reviewed for scoring and quality assurance.

- **Please initial your choice below:**

_____Yes, I grant permission for my child to be videotaped during the developmental assessments which will be used in the analysis phase of the study data.

_____No, I do not grant permission for my child to be videotaped during the developmental assessments which will be used in the analysis phase of the study data.

Permission to share data with NDAR (National Database for Autism Research):

Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer medical research information system or database run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before.

During and after the study, the researchers will send information about your child's health and behavior and in some cases, your child's genetic information, to NDAR. However, before they send it to NDAR, they will remove information such as name, address, and phone number, and replace that information with a code number. Other researchers can then file an application with the National Institutes of Health to obtain access to your child's study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

Your child may not benefit directly from allowing information to be shared with NDAR. The information provided to NDAR might help researchers around the world treat future children and adults with autism spectrum disorders so that they have better outcomes. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you or your child individually about specific studies. You may decide now or later that you do not want to share your child's information using NDAR. If so, contact the researchers who conducted this study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Your child's coded genetic and health information may be put in one or more of the controlled-access databases and used for future research. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. We will replace this identifying information with a code number. We will keep a master list that links your code number your identifying information here at the University of Alabama at Birmingham (UAB). Only certain research staff members are UAB will have access to this master list. Researchers approved to access information in the controlled-access data base

will agree not to attempt to identify you.
Your child does not have to share data with NDAR in order to be in this research study.

Please initial your choice below:

_____ Yes, I grant permission for data to be shared with NDAR.

_____ No, I do not grant permission for data to be shared with NDAR.

Data Sharing

Data from this research will be shared with other researchers at other institutions. Data sharing is important for further understanding of research results to improve human health. All links with your identity will be removed from the data before they are shared.

Data will be sent electronically by a secure database to a data coordinating center at UAB to perform data tracking and analysis.

Please initial your choice below:
___ I agree to allow my child's data to be shared.

___ I do not agree to allow my child's data to be shared.

Genomic Data Sharing: Unless you specify otherwise, we may place some of your child's genetic and health information into the national scientific database known as dbGaP (see http://www.ncbi.nlm.nih.gov/gap). dbGaP is a database set up by the National Institutes of Health that includes health and genetic information from many thousands of people. Access to dbGaP is available only to qualified researchers at qualified institutions that agree to a variety of privacy-guarding safeguards. Researchers given access to this information have both a legal and ethical duty to protect your child's privacy and to keep your child's information confidential. However, because your child's genetic information is unique to him/her, there is a small chance that someone could trace it back to him/her. The risk of this happening is very small, but may grow in the future. Please tell the research staff if you do not want your child's information to be placed into dbGaP.

Controlled-Access Databases: Your child's information may be put in controlled-access databases. This means only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your child's information stored in these databases will not include any identifying information. We will replace identifying information with a code number. We will keep a master list that links your child's code number to your child's identifying information here at the UAB. Only certain study personnel for this study at UAB will have access to this master list. Researchers approved to access information in the controlled-access database will agree not to attempt to identify your child.

Risks: The risk of sharing your child's genomic data is that someone could link the information stored in the databases back to your child. If your child's information suggested something serious about his/her health, it could be misused. For example, it could be used to make it harder for your child to get or keep a job or insurance or be used to discriminate against your child or your family. There may also be other unknown risks.

Benefits: There is no direct benefit to you from sharing your child's genomic data. Allowing researchers to use your child's data may lead to a better understanding of how genes affect health. This may help other people in the future.

Please initial your choice below:

___ I agree for my child's genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

___ I do not agree for my child's genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

Consent to Re-contact

It may be beneficial to the goals of this study for physicians to re-contact you to keep you up to date about the study and to check on your child's progress. However, consenting to re-contact by qualified individuals is not a requirement for study participation.

By initialing here you agree to allow re-contact: _____
Initials of Participant

Signatures

You are making a decision whether or not to allow your child to participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate. You will receive a copy of this signed document.

The assent of _____ (name of child/minor) was waived because of age.

_____

Signature of Parent or Legally Authorized Representative Date

_____

Signature of Parent or Legally Authorized Representative Date

_____

Signature of Person Obtaining Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH (MINOR PARTICIPANT)

Participant Name: _____
Research Protocol: PREVENTING EPILEPSY USING VIGABATRIN IN INFANTS WITH TUBEROUS SCLEROSIS COMPLEX (PREVeNT TRIAL) A randomized, double-blind, placebo-controlled seizure prevention clinical trial for infants with TSC

UAB IRB Protocol Number: IRB-160509001
Principal Investigator: Martina Bebin, MD, MPA
Sponsor: National Institute of Neurological Disorders and Stroke (NINDS)

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____