

PARENT/SURROGATE SUBJECT CONSENT FORM

ANN & ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO

INSTITUTIONAL REVIEW BOARD

Permission for a Child to Participate in a Research Project

Investigators at Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) invite you to consider participating in a research study entitled:

Rapid-Onset Obesity, Hypothalamic Dysfunction, Hypoventilation, and Autonomic Dysregulation: Biomarkers Study

carried out by Debra E. Weese-Mayer, MD and her colleagues at Lurie Children's, in Chicago, Illinois.

This consent form describes a study being done at Lurie Children's. Research studies help us learn more about conditions and possible new treatments. Research studies are voluntary, which means that it is your choice whether to allow your child to participate in the study. The study staff will also explain the study to you and answer any questions that you may have before you make a decision.

WHY IS THIS STUDY BEING DONE?

Your child is being invited to take part in a research study at Lurie Children's. This form provides you with information so you can understand the possible risks and benefits of participating in this study; so that you can decide whether or not you want your child to be a part of this research study. Before deciding whether to allow your child to participate in this study, you should read the information provided on this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to allow your child to participate.

The purpose of the research is to look for gene(s) or biomarkers that result in or contribute to Rapid Onset Obesity with Hypothalamic Dysfunction, Hypoventilation, and Autonomic Dysregulation (ROHHAD). ROHHAD is a disease of unknown cause resulting in rapid onset obesity, hypothalamic and autonomic nervous system dysfunction, and hypoventilation among other symptoms. Biomarkers are biological molecules found in blood, body fluids, or tissues that are a sign of a condition or disease. These biomarkers may determine how likely and how severely we are to get certain diseases and disorders. The biomarkers responsible for ROHHAD remains unidentified at present. In order to participate in this study, your child was already identified as having ROHHAD with no *PHOX2B* mutation but confirmatory record review.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL MY CHILD BE IN THE STUDY?

First, if your child has ever had any tumor tissue removed or cord blood/tissue stored, we will ask that you allow us to obtain this tissue and/or blood for further genetics research. You may have to contact the hospital or institution where this surgery or storage took place to request that we be allowed to obtain this tissue and/or blood. Then, your child will be sent a buccal sample
Parent of Proband

kit. We will ask your child to provide a buccal sample with the kit by swabbing the inside of your child's cheek. Next, the child with ROHHAD will have a blood draw of up to 10 cc (about 2 teaspoons), with blood collected in a purple top tube and in a red top tube. If the child with ROHHAD does not wish to provide a blood sample, your child will be mailed a saliva sample kit and your child will be asked to provide a saliva sample with the kit. To qualify for participation in this research project your child's blood sample should already have been studied with the clinical *PHOX2B* Sequencing Test. Because that clinical test is negative, your child meets entry criteria for this research study, but we will need your permission to use the remaining blood for this research project. The blood samples (or saliva samples if blood draws are not possible) from the parents will be drawn solely for this research project. These blood draws will most likely take place under the care of your current medical provider. Blood, tissue, saliva, and buccal samples will then be shipped to Dr. Larry Jennings at Lurie Children's, Dr. Elizabeth Berry-Kravis at Rush University Medical Center, or Dr. Torben Bech-Hansen at University of Calgary where biomarkers, such as DNA and RNA, will be isolated and analyzed. We will use the DNA isolated from these samples for future genetic analysis, including Sanger, Exome, Whole Genome, and other sequencing methods. We will save your child's biomarkers to do further genetic testing. Your child's specimen will be stored either at Lurie Children's Hospital, at University of Calgary, or at Rush University Medical Center in Chicago. You may choose to receive the results of your tests. You do not need to receive results if you do not want them.

ARE THERE BENEFITS (GOOD THINGS) TO TAKING PART IN THE STUDY?

There may be no immediate benefit to your family as a result of this study. However, the potential development of new tests, treatment and information may be beneficial to the care of ROHHAD patients and families in the future.

WHAT ARE THE POSSIBLE RISKS OR SIDE EFFECTS (BAD THINGS) OF THE STUDY?

The blood draw may cause discomfort, bleeding, or bruising at the site where the needle enters the body (normally the arm). In rare cases, fainting or infection may occur. We will take care to use sterile technique and experienced personnel to draw blood.

Unforeseen risks: It is difficult to predict whether your child will experience any complication from participating in this research. A potential risk might be the release of information from your child's health or study records. Reports about research done with your child's samples will not be put in their health record, but will be kept with the study records. The study records will be kept confidential as far as possible within state and federal law. There is always a small risk that an unauthorized person could view your child's results and link them to him or her.

There is a federal law, the Genetic Information Nondiscrimination Act (GINA) and an Illinois state law, the Genetic Information Privacy Act (GIPA), that both aim at banning discrimination by health insurance companies, group health plans, employers, labor unions, and employment agencies on the basis of genetic testing information. You should be aware that these laws do not prohibit discrimination on the basis of an existing (already-diagnosed) genetic disease or disorder. In addition, these laws do not protect you against use of genetic testing information by companies that sell life insurance, disability insurance, or long-term care insurance. For more

information about GINA, see <http://www.hhs.gov/ohrp/policy/gina.html>. For more information about GIPA, see <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1567&ChapterID=35>.

WHAT OTHER OPTIONS ARE THERE?

The only alternative to participating in this study is not to participate.

WHAT ARE THE COSTS?

If you choose to allow your child to participate in this study, we will provide the professional services required to obtain and analyze these samples (and other research samples) for the research tests only at no cost to you. Expenses related to routine health check-ups and care for any problem your child may have are your responsibility (or the responsibility of your insurance provider or government program). There are no funds available to pay for lost time away from work and other activities, lost wages, or child care expenses.

WILL I BE TOLD ABOUT NEW INFORMATION?

The investigator will inform the participants of significant new findings which come to light, during the study, which might affect the participant's willingness to participate in the research.

WILL THERE BE COMPENSATION FOR MY CHILD'S PARTICIPATION?

Your child will be compensated for participation in this study. You will be mailed gift card(s) in the amounts specified based on which samples your child has provided and which samples have been safely received by the research team. Buccal samples will be compensated with \$20, blood samples will be compensated with \$100, tumor tissue and/or cord blood/tissue will be compensated with \$50. Your child's samples will be used only for research and will not be sold or used directly for the production of commercial products. However, in some research, the samples may enable researchers to develop medical tests that have commercial value. You will not receive any money that may result from any such commercial tests.

WHAT DO I DO IF MY CHILD IS INJURED?

If your child is injured, medical facilities and treatment will be available. However, you will be required to pay a reasonable fee for such care. Your child can still receive medical benefits if otherwise entitled. If you have any questions or desire further information concerning the availability of medical care, you may contact Dr. Michael Kelleher, Chief Medical Officer, Lurie Children's, 225 East Chicago Avenue, Box #2, Chicago, Illinois, 60611, (312) 227-4270.

WHO WILL KNOW ABOUT WHAT MY CHILD DID IN THE STUDY OR HAVE ACCESS TO MY CHILD'S PRIVATE INFORMATION?

The purpose of clinical studies is to collect medical information from a group of research subjects in order to better understand the disease or condition being studied. Therefore, the investigators/researchers will need access to the medical records and results of this study of all of the children who participate in this study.

If you sign this consent form, you are giving permission for your child's physician and Lurie Children's to provide your child's medical records to the following people, agencies or companies to review and use in this research study:

- 1) Lurie Children's study staff

- 2) Lurie Children's Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who participate in research studies at Lurie Children's)
- 3) Representatives of the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) or other regulatory agencies
- 4) Dr Elizabeth Berry-Kravis at Rush University Medical Center
- 5) Dr. Paul Gray at Washington University
- 6) Dr. Richard Wilson, Dr. Torben Bech-Hansen, Dr. Kyle Kurek, and Dr. Marvin Fritzler at University of Calgary

Lurie Children's and your child's doctors will keep the records of this study confidential, and will release your child's medical information only to the people or companies listed above. Before any of your child's information is shared with these people, the information will be deidentified (your child's name will be removed from the information, and replaced with a study number). However, it is important for you to understand that, once your child's doctor or Lurie Children's releases your child's medical information to these people or companies, your child's doctor or Lurie Children's cannot then guarantee that your child's information will remain confidential. It is possible that these other persons, organizations, or companies could give your child's study information to others, without your permission.

The records of this study will be kept confidential with respect to any written or oral reports to the profession or the media, making it impossible to identify your child individually.

This signed consent form will be placed in your child's medical record at Lurie Children's with a copy placed in the Principal Investigator's research file. If your child does not have a medical record at Lurie Children's, then this signed consent form will only be kept in the Principal Investigator's research file.

WHAT ARE MY CHILD'S RIGHTS AS A PARTICIPANT?

By signing this consent form, you agree to have your child take part in this study. You are not giving up any of your or your child's legal rights or releasing this hospital from responsibility for carelessness.

You may cancel your consent and take your child out of this study at any time. Neither you nor your child will be penalized for doing this. Your child's treatment by, and relations with the physician(s) and staff at The Lurie Children's, now and in the future, will not be affected in any way if you do not want your child to take part in this study, or if you enter your child into the study and then withdraw your child from it.

If you wish to withdraw permission to participate in this study, write to Dr. Weese-Mayer and let her know that you are withdrawing your child from the research study. Her mailing address is:

D. E. Weese-Mayer, M.D.
Center for Autonomic Medicine in Pediatrics (CAMP),
Ann & Robert H. Lurie Children's Hospital of Chicago
225 East Chicago Avenue, Box 165,
Chicago, Illinois 60611-2605

At any time, you can tell your child's doctor or Lurie Children's not to use or give out your child's study information or other information from your child's medical record to other people, organizations, or companies. Withdrawal of this permission must be in writing. Any study information or other information from your child's medical record collected before your written notice of permission withdrawal may still be used for the study, if that information is necessary for the study. Because the purpose of this study is to collect information about how well the study drug or treatment works, if you refuse to release your child's study information, your child may not be able to start, or continue taking part in this study. Your decision will not affect your child's regular care and your child's doctors will not change their feelings about you.

If you agree to let your child take part in this research study, you will not be able to look at or ask for a copy of your child's health information collected only for this study, while your child is taking part in the study. If you wish, you will be able to ask for this study research information when the study is over or when your child is no longer taking part in the study. This does not affect your right to see your child's medical record or the results of tests related to regular medical care that is given during the same time as the research study.

If you have or your child has any questions about the research methods, you should contact the principal investigator, Debra E. Weese-Mayer, MD at (312) 227-3300

If you have any questions about your child's rights as a research subject, wish to discuss problems, concerns, and questions, wish to obtain information, or wish to offer input to someone who is not directly involved with this study, you may contact Philip V. Spina, Sr. Vice-President and Chief Operating Officer, Ann & Robert H. Lurie Children's Hospital of Chicago Research Center, 225 East Chicago Avenue, Box #205, Chicago, Illinois 60611 (Phone: (773)755-6301; Fax: (773)755-6533; E-mail: pspina@luriechildrens.org).

You will be given a signed and dated copy of this consent form.

OPTIONAL TESTING/BANKING

While your family is in this study, your child's sample may not be totally used for this research study and the left over sample may be useful for future research. Should we need to test this sample further, we are asking your permission to complete further testing related to ROHHAD on your child's sample. The results of any future tests that may be performed will be used for research purposes only and they will not be given to your private doctor or anyone else. Nor will they be put into your child's medical records. The test results, unlike medical testing, are experimental and preliminary and, for this reason, will not be provided to you. This sample will be stored at the institution that is performing this research, and will be used by these investigators only.

If you do not want to let researchers store your child's samples for future research studies, the remaining sample will be destroyed. If you withdraw your child or are removed from the clinical study, for any reason, the sample will be destroyed and the results will not be used.

Please initial below how you wish to allow your child's sample to be utilized in the following way: (choose one only).

_____ The sample(s) can be used for *BOTH* the current research study and future research to learn more about diseases of RADICA, *AND* it can be used for other research.

_____ The sample(s) can be used for the current genetic research study *ONLY*.

_____ The sample(s) can be used for *BOTH* the current research study and future research to learn more about diseases of RADICA, but it will *NOT* be used for any other research.

SIGNATURES

The study has been explained to me and I have read this consent form, have been given the opportunity to consider my decision, and have had all my questions answered. I agree to have my child take part in this study as explained in this consent form. I agree to let my child’s doctor or Lurie Children’s use and give out my child’s health information in the way it is described in this consent form until the end of the research study.

_____ Date _____ Signature of Parent or Legally Authorized Representative (LAR)

_____ Printed name of child _____ Printed name of parent/LAR _____ Relationship to child

I certify that I have explained the above to the parent(s) and/or surrogate(s) and believe that the signature(s) was affixed freely. I also agree to answer any questions that may arise.

_____ Date _____ Signature of Person Obtaining Consent (PI or designee)

_____ Printed Name of Person Obtaining Consent (PI or designee)

INTERPRETER/WITNESS SIGNATURE:

Complete only when obtaining consent from a non-English speaking parent/LAR: Use a translated short form along with this document. The participant should sign the short form; the interpreter/witness should sign both; and the person obtaining consent should sign this form.

By signing this consent and the translated short form, I attest that the elements of informed consent were presented verbally to the parent(s)/LAR in their native language. He/she was given the opportunity to have all questions answered. Consent was obtained freely as is indicated by his/her signature on the short form.

_____ Printed Name of Interpreter/Witness _____ Signature of Interpreter/Witness
May be the interpreter, but cannot be the same as the person obtaining consent. *Or the unique ID# of the phone interpreter and his/her company name*

Approved by IRB on: 1/13/17
IRB Approval Expires on: 12/31/17
Lurie Children’s IRB#: 2009-13904
Stamped by: EE