ADULT SUBJECT CONSENT FORM

ANN & ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO
INSTITUTIONAL REVIEW BOARD
Adult Subject Consent 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 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?
You are 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 to be a part of this research study. Before deciding whether 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 participate.

The purpose of the research is to look for actual gene(s) or biomarkers that result in 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.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL I BE IN THE STUDY?
First, if you have 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, you will be sent a buccal sample kit. We will ask you to provide a buccal sample with the kit by swabbing the inside of your cheek. Next, you are responsible for allowing 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. To qualify for participation in this research project your blood sample will first be studied with the clinical *PHOX2B* Sequencing Test. If

that clinical test is negative, then we will need your permission to use the remaining blood for this research project. This blood draws will most likely take place under the care of your current medical provider. If you do not wish to provide a blood sample, you will be mailed a saliva sample kit and we will ask you to provide a saliva sample with the kit. 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 biomarker, such as DNA and RNA, will be isolated and analyzed. We will use the biomarkers isolated from these samples for future genetic analysis, including Sanger, Exome, Whole Genome, and other sequencing methods. We will save your biomarkers to do further genetic testing. Your 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 you 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 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 you will experience any complication from participating in this research. A potential risk might be the release of information from your health or study records. Reports about research done with your 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 results and link them to you

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?
Neither you nor your insurance company is responsible for costs associated with any tests, procedures and/or medications done for research purposes only. However, you and/or your insurance company are still responsible for the usual, ongoing medical care that is necessary to treat your medical condition. If you choose 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.
Lurie Children's may be able to provide some financial assistance to eligible patients. To obtain more information about this program, ask your healthcare team or visit the website http://luriechildrens.org/en-us/care-services/billing-medical-records/Pages/financial-assistance.aspx.

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 I BE COMPENSATED FOR MY PARTICIPATION?
You will be compensated for your participation in this study. You will be mailed gift card(s) in the amounts specified based on which samples you have 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 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 I AM INJURED?
If you are injured, medical facilities and treatment will be available. However, you will be required to pay a reasonable fee for such care. You 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 I DID IN THE STUDY OR HAVE ACCESS TO MY 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 of all who participate in this study.

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

1) 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)

2) Representatives of the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) or other regulatory agencies
3) Dr Elizabeth Berry-Kravis at Rush University Medical Center
4) Dr. Paul Gray at Washington University
5) Dr. Richard Wilson, Dr. Torben Bech-Hansen, Dr. Kyle Kurek, and Dr. Marvin Fritzler at University of Calgary

Lurie Children's and your doctors will keep the records of this study confidential, and will release your medical information only to the people or companies listed above. However, it is important for you to understand that, once your doctor or Lurie Children's releases your medical information to these people or companies, your doctor or Lurie Children's cannot then guarantee that your information will remain confidential. It is possible that these other persons or companies could give your 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 you individually.

This signed consent form will be placed in your medical record at Lurie Children's with a copy placed in the Principal Investigator's research file. If you do 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 RIGHTS AS A PARTICIPANT?

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

You may cancel your consent and take yourself out of this study at any time. Neither you nor you will be penalized for doing this. Your 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 to take part in this study, or if you enter you into the study and then withdraw you 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 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 doctor or Lurie Children's not to use or give out your study information or other information from your medical record to other people, organizations, or companies. Withdrawal of this permission must be in writing. Any study information or other information from your 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. Your decision will not affect your regular care and your doctors will not change their feelings about you.

If you agree to let you take part in this research study, you will not be able to look at or ask for a copy of your health information collected only for this study, while you are 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 you are no longer taking part in the study. This does not affect your right to see your 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 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 rights as a participant in a research study (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 Office, 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 you are in this study, your 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 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 medical record. 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 sample for future research studies, the remaining sample will be destroyed. If you withdraw 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 samples 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 take part in this study as explained in this consent form. I agree to let my doctor or Lurie Children's use and give out my health information in the way it is described in this consent form until the end of the research study.

Date	Signature of Participant (≥18 years) or Legally Authorized Representative (LAR)
	Printed Name of Research Subject or LAR

I certify that I have explained the above to the subject 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 participant/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 *May be the interpreter, but cannot be the same as the person obtaining consent.*	Signature of Interpreter/Witness *Or the unique ID# of the phone interpreter and his/her company name*