CHILD'S/ADOLESCENT'S SUBJECT ASSENT FORM

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

INSTITUTIONAL REVIEW BOARD

Adolescent's Agreement to Participate in a Research Study
Ages 12- 17

We are asking you to be in a research study called:
Rapid-Onset Obesity, Hypothalamic Dysfunction, Hypoventilation, and Autonomic Dysregulation: Biomarkers Study
carried out by Debra E. Weese-Mayer, MD and her colleagues at Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's).

WHY IS THIS STUDY BEING DONE?

We want to tell you about a research study at Lurie Children's. Research studies help us find better ways to take care and treat children who are sick with a disease, to learn how medicines work, and how our bodies work. We would like to ask you for your help. Research studies are voluntary, which means that you only have to participate in the study if you want to.

We are asking you to be in this research study because you have ROHHAD (an easy way to say: "Rapid-Onset Obesity with Hypothalamic Dysfunction, Hypoventilation, and Autonomic Dysregulation"). If you choose to be a part of the study you will be a big part of helping us learn about this disease and to hopefully come up with better ways to treat people with ROHHAD.

Reading through this form and asking questions will help you understand what you would need to do to help us. After you read through this form and ask any questions about things you don't understand or are confused about, we will ask you to give us your permission to be included in the study by signing this paper. You will only sign the paper if

1) you decide you want to be included in the study
2) you are sure you understand everything in this paper

WHAT HAPPENS IN THE STUDY AND HOW LONG WILL I BE IN THE STUDY?

If you want to be in the study, this is what will happen: first, if you have ever had tissue removed from any surgery or your cord blood/tissue was stored after your birth, we will ask for permission to obtain and use this tissue, cord blood, and/or cord tissue in our biomarkers study. Your family may need to contact your current medical provider to request that the tissue, cord blood, and/or cord tissue be sent.

Then, you will be sent a buccal sample kit. You will use the swab to wipe the inside of your mouth.

Next, a health care provider will perform a blood draw on your arm of up to 10 cc (about 2 teaspoons). This will most likely take place at your doctor's medical office or hospital. Blood will then be shipped to Lurie Children's, Rush University Medical Center, or University of Calgary where biomarker isolation and analysis will take place. We will use the biomarkers

(such as DNA or RNA) isolated from your sample for future genetic analysis, including Sanger, Exome, Whole Genome, and other sequencing methods. We will save your biomarkers to do further genetic testing, either at Lurie Children's or at Rush University Medical Center in Chicago, IL. You may choose to receive the results of your testing. You do not need to receive results if you do not want them.

WHAT ARE THE GOOD THINGS ABOUT THE STUDY?
You will not benefit directly from this study now, we hope to learn something that could help other children in the future who have ROHHAD.

WHAT ARE THE NOT-SO-GOOD, BAD, OR HARMFUL THINGS THAT COULD HAPPEN TO ME IF I AGREE TO BE IN THIS STUDY?
When we take blood from your arm, it might hurt a little and you might get a bruise.

We will tell you if we learn new information that may make you change your mind about being in this study.

WHAT OTHER OPTIONS ARE THERE?
You do not have to be in this study if you don't want to. Your doctors will not be upset with you. If you join the study and then change your mind, it is okay for you to leave this study.

WHAT ABOUT MY CONFIDENTIALITY?
We will do everything possible to make sure that your medical records are kept private.

Unless required by law, only representatives of the following groups or organizations can review your study records.

- Lurie Children's study staff
- The Lurie Children's Institutional Review Board (IRB): This is the hospital's board that is in charge of protecting the rights of all adults and children who participate in research studies.
- Government agencies with responsibilities to oversee research studies.
- Members of the study team including: 1) Dr. Weese-Mayer and her staff at Lurie Children's, 2) Dr. Elizabeth Berry-Kravis at Rush University, 3) Dr. Paul Gray at Washington University, and 4) Dr. Richard Wilson, Dr. Torben Bech-Hansen, Dr. Kyle Kurek, and Dr. Marvin Fritzler at University of Calgary

They are required to keep your personal information private.

WILL I RECEIVE ANY PAYMENT OR GIFTS IF I AM IN THIS STUDY?
You will receive a $20 gift card for the buccal sample, $100 for the blood samples, $50 for tumor tissue and/or cord blood/tissue from being in this study.

WHAT IF I HAVE QUESTIONS?
You can ask questions whenever you have them. You can ask your doctor, nurse or other people working with them on the study. You can also ask your parents.

Your parents know about this study and say that it is okay if you want to be in the study. If you don't want to be in the study, that is okay.

You can ask Dr. Weese-Mayer anything about the study. Her phone number is 312-227-3300 and her email address is: DWeese-Mayer@LurieChildrens.org. If you are not happy with this study and want to talk with someone else, not the doctor or the people working with the doctor, you may contact Philip V. Spina, Senior Vice-President and Chief Operating Officer at Ann & Robert H. Lurie Children's Hospital of Chicago Research Center, at (773)755.6301 or pspina@luriechildrens.org. His address is 225 East Chicago Avenue, Box # 205, Chicago, Illinois 60611.

You will be given a copy of this form.

SIGNATURES

The study has been explained to me and I have read this assent 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 assent form.

_____	_____
Date	Signature of Adolescent (only 12-17 years old)
	_____
	Printed Name of Adolescent
_____	_____
Date	Signature of Person Obtaining Assent (PI or designee)
	_____
	Printed Name of Person Obtaining Assent (PI or designee)

WHEN IT IS NOT POSSIBLE TO OBTAIN WRITTEN ASSENT

If the adolescent is **unable to give written assent**, but is able to **verbally** agree to participate in the study, thoroughly document the assent process and proceed.

If the adolescent is **unable to provide assent (written and verbal)**, a waiver of assent must be obtained from the IRB chair. Please send an e-mail documenting the circumstances and the request to the IRB.