

**UNIVERSITY OF CALIFORNIA, IRVINE**  
**ASSENT TO BE IN A HUMAN RESEARCH STUDY**  
**Form 2**

**Prader-Willi Syndrome and Early-onset Morbid Obesity Natural History Clinical Protocol**

Participating in this study is totally voluntary. Please read about the study below. Feel free to ask questions about anything that you do not understand before deciding if you want to be in the study. A researcher listed below will be around to answer your questions. This form is intended for children over the age of 7 years who can read and understand the form.

**RESEARCH TEAM**

**Lead Researcher:**

Virginia Kimonis, Professor of Pediatrics  
Telephone Number: 714-456-5792  
24 Hour Telephone: 949-266-7946

**Study Locations:**

Institute for Clinical & Translational Science (ICTS), University of California, Irvine CA  
Institute for Clinical & Translational Science (ICTS), UC Medical Center, Orange, CA  
Children's Hospital of Orange County (CHOC)

**WHY ARE YOU HERE?**

I am Dr. Virginia Kimonis. I work at the University of California, Irvine in the Division of Genetics of the Department of Pediatrics. I want to tell you about a study that involves children like yourself or your brother or sister. We want to see if you would like to be in this study. Prader-Willi syndrome and early-onset morbid (severe) obesity are rare disorders and it is hoped that research will help in understanding and improving the treatment of these disorder. We would like to see you every two years and ask you questions about your health, perform a physical examination, take photographs, perform intelligence and other studies to monitor how you change over the years.

**WHY ARE THEY DOING THIS STUDY?**

Dr. Kimonis is doing this study to learn more about people with the problems that you have. The doctors and adults may call this Prader-Willi syndrome or early onset morbid obesity, which is sometimes shortened to EMO and can affect a person throughout his or her life, from birth to adulthood. Many factors will be studied such as comparing different types of Prader-Willi syndrome with each other and with other rare conditions that cause you to be overweight. The study will look at the effect of the age of starting treatment with growth hormone and the age of diagnosis etc. It is hoped that by studying many individuals with a rare disorder that better recommendations for treatment may be available in the future.

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Approved by IRB on: 03/18/11

HS# 2007-5605

Void After: 03/17/12

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## **WHAT WILL HAPPEN TO YOU?**

Your parent or guardian had the whole study explained to them, and they agree for you to be part of it. You can say no to any part of the study that you don't want to do. This is part 2 of a 2 part study. Part 1 was looking at your medical record to make sure you are eligible to join the study. These things will happen if you want to be in the study:

1. You will have a physical examination by Dr. Kimonis, including measuring your height and weight, body measurements, and skin fold measurements; listening to your heart; testing your arm and leg responses with a soft hammer, and examination of your face and the rest of your body, including your genitalia. This will take about 30 minutes.
2. Your parent or guardian will be asked to fill out a form with questions about your health and developmental milestones and also the skills you possess.
3. You may be asked questions to test your spoken and other non-spoken skills which are tests of intelligence.
4. You may have photographs taken of yourself (if your parents decide it is okay) so that your appearance can be compared with that of other participants and so that the study team can see how you change from year to year. Photographs of the front and side of your face and body will be obtained. If the results of this study are published or presented at scientific medical conferences, you will not be identified by name. However, if you agree to allow the study team to take pictures of you, it is possible that people who know you might recognize you. We will not share your name or any other identifying information with the photographs and other information collected as part of this study with other researchers.
5. You will have a blood test. A Nurse will take a small amount of blood from your arm. This will be a very small amount, about 1 to 4 teaspoons depending on how old you are. Most people over 7 years of age will have 3-4 teaspoons taken. A DEXA scan to measure your bones is part of this study. This is a kind of X-ray, for this you will have to lie down for about 15 to 20 minutes.

## **WILL THE STUDY HURT?**

The study is not expected to hurt. There will be a little pain from the blood test which may be done only once in the study. It may be difficult to keep still for the scan but it is not painful.

Answering questions regarding your medical history, diet, eating, behavior, mood, sleeping and the physical examination may make you feel embarrassed or uncomfortable.

Taking photographs of your body may make you feel a little uncomfortable and you do not have to have the pictures taken if you do not want to.

There is potential risk of loss of privacy associated with photographs of your face and body. However we will make every effort to remove all identifying information



**WILL YOU GET BETTER IF YOU ARE IN THE STUDY?**

This study won't make you feel better. But, the doctors might find out something that will help other children with PWS and EMO.

**IF YOU HAVE ANY QUESTIONS**

You can ask questions any time. You can ask now or you can ask later. You can talk to the doctors/researchers, your mom and dad, or you can talk to someone else.

**DO YOU HAVE TO BE IN THE STUDY?**

You do not have to be in the study. No one will be mad at you if you don't want to do this. If you don't want to be in this study, you just have to tell the doctor/researchers. If you want to be in the study, you just have to tell them. You can say yes now and change your mind later. It is up to you to decide.

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Signature of Child

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Age

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Date

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Signature of Researcher

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Date

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Signature of Witness

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Date

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