**UNIVERSITY OF CALIFORNIA, IRVINE**
**ASSENT TO BE IN A HUMAN RESEARCH STUDY**
**Form I: Review of Medical Records**

**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.

## RESEARCH TEAM

**Lead Researcher:**
Virginia Kimonis, MD
Chief, Division of Genetics and Metabolism
Professor of Pediatrics
Department of Pediatrics
Telephone Number: (714) 456-5792
24 Hour Telephone: (714) 506-2063 (Pager)

**Study Locations:**
Institute for Clinical & Translational Science (ICTS), University of California, Irvine CA
Institute for Clinical & Translational Science (ICTS), UC Medical Center, Orange, CA

## WHY ARE YOU BEING CALLED?

I am Dr. Virginia Kimonis. My study team and 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 brothers and sisters. I want to see if you would like to participate in this study.

## WHY ARE THEY DOING THIS STUDY?

I am studying why people are born with problems like you to learn more about how Prader-Willi syndrome and other rare conditions that can cause severe problems of being over weight (sometimes shortened to EMO) can affect a person throughout his or her life, from birth to adulthood. Many factors will be studied such as the comparison of different types of Prader-Willi syndrome with each other and with EMO, 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. People with those problems or their siblings and parents may join this research study. I hope to find what causes these problems so that physicians can help other children who have the same or similar problems.

**WHAT WILL HAPPEN TO YOU?**
There are two parts to this study. This is part one where we call and explain to you that we would like to look at your medical records. To find out if it is appropriate for you to enter the study.
Part two will happen after part one and if you decide to be in the study, when you come for the first appointment every thing will be explained to you and you will then need to sign another consent form in person with your parents.

**WILL THE STUDY HURT?**
This part of the study will not hurt.

**WILL YOU GET BETTER IF YOU ARE IN THE STUDY?**
You will not get better if you are in the study. If you decide not to participate you will receive the same medical care as if you are participating. There are no direct benefits for you, but if you participate the study team may learn more about your condition and may be able to help other kids with the same problem better in the future.

**DO YOU HAVE TO BE IN THE STUDY?**
No, you don't. No one will get angry or upset if you don't want to be in the study. Just tell me. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

**DO YOU HAVE ANY QUESTIONS?**
You can ask questions at any time. You can ask now. You can ask later. You can talk to me any time during the study. Here are the telephone numbers to reach

Dr. Virginia Kimonis
Telephone Number: (714) 456-5792
24 Hour Telephone: (714) 506-2063 (Pager)

| | | |
|---|---|---|
| Signature of Child | Age | Date |
| Signature of Researcher | | Date |
| Signature of Witness | | Date |