UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT FOR RELEASE OF MEDICAL RECORD REVIEW
Form 1

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

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

Participation in this study is completely voluntary. Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM AND SPONSORS

Lead Researcher:
Virginia Kimonis, MD
Chief, Division of Genetics and Metabolism
Professor of Pediatrics
Tel: (714) 456-2942,
24 Hour Telephone: (714) 506-2063 (Pager)
Email:vkimonis@uci.edu

Study Locations:
UCI ICTS, UCI Medical Center
CHOC

Study Sponsor: NIH

PURPOSE OF STUDY

The purpose of this study is to collect natural history information on Prader-Willi syndrome and early-onset morbid (severe) obesity to learn more about how these conditions can affect a person throughout his or her life, from birth to adulthood. This is a group effort involving other hospitals. The information will be stored here at the University of California, Irvine, and at the Data and Technology Coordinating Center at the University of South Florida in Tampa, Florida.

WHY IS THIS RESEARCH?

This is a research study because the researchers are interested in learning more about your condition/disorder. 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 disorders. Only by studying a large number of patients with a rare disorder can meaningful data be obtained that will help patients.

At this time we are only asking permission for medical records review.

Study Design
Initially we would only like to formally ask your permission to review your medical records. This is done to see if you fulfill the criteria to enter the study as well as to have all of your records on hand at your visit which will then require less time.

We will obtain permission to access your medical records over the phone. You have therefore been sent this consent form, a medical information release form and a HIPAA form which is concerned with privacy issues. Please read these forms and we will go over them with you on the telephone and answer all of your questions. Once we have reviewed your medical records you will be invited to be seen in clinic and full explanation and consent will be obtained at this time including details of all procedures. Please be aware that if no date is specified the authorization expires 12 months from the date the form is signed.

SUBJECTS
Inclusion Requirements
You are eligible to participate in this study if:
You have Prader-Willi syndrome (PWS) or Early-onset childhood Morbid Obesity (EMO).

PROCEDURES
We wish to obtain relevant medical records from you or your physician(s). We would like you to sign a medical record release form so that we may review medical records that are important to our research. Whenever possible, a review of medical records will be completed prior to the study visit to limit the length of the visit. This is why we are asking you to sign this consent form for release of medical information in addition, a medical release form and a UCI HIPAA form for research studies will therefore be mailed to you before your appointment. Once we receive the signed forms back from you we can start to obtain medical records.

The additional procedures will be explained at the first visit and a comprehensive consent will then need to be signed by you or by both parents for children who participate. The signature of at least one parent is sufficient if one of the parents is deceased, unknown, incompetent, or not reasonably available, otherwise both parents need to sign the consent form for their child.

RISKS AND DISCOMFORTS
The only risk to this part of the study is privacy and possible breach of confidentiality. This is because personal information about you will be collected. This is extremely unlikely and of course all efforts will be made to minimize this possibility. Your medical records will only be reviewed by Dr. Kimonis and the study team. If genetic information is released to others or your physician with your permission, this information may be included in your medical record. A copy of this consent form will NOT be placed in your medical record.

BENEFITS
Subject Benefits
There is no direct benefit to you from being in this study. However, we hope that the information obtained may help us in the development of accurate and efficient diagnostic testing and better

treatment strategies for people with these conditions. The information obtained may also potentially benefit the subjects in the future.

Benefits to Others or Society
Benefits for society are potentially great if the scientific and health communities gain information about the syndrome genes, their function as they relate to normal craniofacial development and the pathogenesis of these conditions.

ALTERNATIVES TO PARTICIPATION
The only alternative is not to participate in this research study. This research study does not involve medical treatment, and will not interfere with any future care you or your family receives at UC Irvine or any referring facility.

COMPENSATION, COSTS AND REIMBURSEMENT
It will not cost you anything to be in this study. You will be compensated $50/visit to cover travel expenses.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES
You are free to withdraw from this study at any time without any obligations or consequences. If you decide to withdraw from this study you should notify your study doctor.

CONFIDENTIALITY
Your research records will be stored in a very restricted-access area.

Subject Identifiable Data
All identifiable information that will be collected about you will be kept with the research data.

Data Storage
Storage of paper files and electronic data: All paper files such as medical records will be maintained in a secure location at UCI. Only authorized individuals will have access to it.

Electronic research data will also be stored on a secure network with password protection
Only de-identified data will be stored at the Rare Disease Clinical Research Network (RDCRN) Data Technology Coordinating Center (DTCC) indefinitely.

Data Access
The research team, authorized UCI personnel and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you unless you have consented to this. If we wish to use identifying information in publications or presentations (i.e., facial photographs), the research team will ask for your approval at that time.

A Certificate of Confidentiality language, has also been added for your protection, so researchers can not be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. However, it can not be used to refuse information from the US government for audits or the FDA, in cases of child abuse, neglect, harm done to you or others, or if you give permission for the information to be released.

Data Retention

The researchers intend to keep the research data at the Data Technology Coordinating Center (DTCC) indefinitely. Other researchers will have access to the data for future research.

NEW FINDINGS

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

OTHER CONSIDERATIONS

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@rgs.uci.edu or in person at 5171 California Avenue, Suite 150, Irvine, CA 92697-7600.

VOLUNTARY PARTICIPATION STATEMENT

You should not sign this form unless you have read the attached "Experimental Subject's Bill of Rights" and have been given a copy of it and this consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I agree to participate in the study.

_____ _____

Subject Signature **Date**

_____

Printed Name of Subject

_____ _____

Legally Authorized Representative/Guardian Signature ***Date***

_____

Printed Name of Legally Authorized Representative/Guardian

_____ _____

Legally Authorized Representative/Guardian Signature ***Date***

_____

Printed Name of Legally Authorized Representative/Guardian

_____ _____

Researcher Signature **Date**

_____

Printed Name of Researcher

_____ _____

Witness Signature ***Date***

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@rgs.uci.edu; or by writing us at 5171 California Avenue, Suite 150, Irvine, CA 92697-7600.