

## UCI Medical Center Clinical Trials Web Page Standard Research Recruitment Advertisement Format

Note: This form must be submitted to the IRB for approval either as part of a new protocol application or with a request for modification to an IRB-approved protocol (electronic Protocol Modification (e-mod) Request can be found at [www.rgs.uci.edu/hs/mod](http://www.rgs.uci.edu/hs/mod)). When you have received approval from the IRB for the advertisement text, please provide a stamped copy to Leanne Spaide, UCI Medical Center, Marketing and Public Relations Department, Rt. 163A, fax (714) 456-8968, for posting on the [www.ucihealth.com](http://www.ucihealth.com) clinical trials Web page.

1. Lead Researcher: Virginia Kimonis MD

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2. Study Title: Prader-Willi Syndrome (PWS) and Early-onset Morbid Obesity (EMO) Natural History Study.

3. 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 an adult. This will mean better management and treatment in the future..

4. Eligibility:

PWS group.

- 1) A confirmed diagnosis of PWS.
- 2) Age 0-60 years.
- 3) All race/ethnic backgrounds.
- 4) Male and Female
- 5) Those receiving and those not receiving growth hormone.

For the EMO group

- 1) Clinical diagnosis made on a medical chart history. Weight greater than 150% of

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ideal body weight (IBW) or body mass index (BMI) of greater than 97% before 4 years of age.

2) Normal chromosomes and tests to rule out other causes of obesity specifically PWS and Fragile X syndrome.

5. Location (if other than UCIMC): General Clinical Research Centers (GCRC) at University of California, Irvine (UCI) and UCI Medical Center.

6. Time Commitment:

Approximately 4 hours. This will include an interview, physical exam, blood draw, bone scan, intelligence and behavioral tests. It is not known for how long this study may continue but at least for 5 years. A yearly appointment until the age of 16 years and then every two years after the age of 16 years.

7. Anticipated Benefits: There may be no direct benefits to the participant at this time. However, long term benefits will mean that we will gain better understanding of PWS and EOM. This could lead to better tests, treatment, therapies and surveillance for the patient/s.

8. Compensation: None

9. Contact Name, UCI Department, Phone Number and E-mail:

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Emergencies after hours or on weekends or holidays: Page Dr. Kimonis at (714) 506-2063

Signature of Lead Researcher: \_\_\_\_\_ Date: \_\_\_\_\_

IRB Approval Granted on:

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