Children's Hospital of Orange County
Study Information Sheet

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

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Study Location(s):
CHOC

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

2. Purpose of the Study:

The purpose of the 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.

3. 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

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

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

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5. 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 3 years and every two years after the age of 3.

6. 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.

7. Compensation: None

8. If you are unable to reach the researcher listed at the top of the form and have general questions, or you have concerns or complaints about the research or questions about your rights as a research subject, please contact CHOC’s Office of Research Compliance by phone, (714) 532-8869, or at 455 South Main Street, Orange, CA 92868.