

Department of Psychiatry

Study Fact Sheet

<u>Study Name:</u> Prenatal Environment And Child Health (PEACH) Study <u>PIs:</u> Elinor Sullivan, PhD and Joel Nigg, PhD <u>IRB#:</u> 18579

Purpose of the Study

The purpose of this study is to learn more about how prenatal factors such as nutrition influence infant and toddler behavior and risk of neurodevelopmental disorders such as attention deficit hyperactivity disorder (ADHD). Child developmental and learning problems such as ADHD are a major public health problem as they place heavy, often lifelong burdens on families, as well as on the nation's educational, health care, and justice systems. This study will determine which prenatal factors are the strongest predictors of alterations in infant and toddler behavior associated with neurodevelopmental disorders, and set the stage for new approaches to prevent or treat child mental health problems.

Duration of the Study

Study participation will last from the beginning of your pregnancy (less than 24 weeks gestation) and will last until your child is 3 years old. There will be a total of 6 study visits (2 during pregnancy and 4 visits with your child) and two optional visits. We will also collect samples of your placenta and umbilical cord blood after your birth, but this will not require any of your time or attention.

What will happen during the study?

If you decide to participate in the study, we will collect blood samples from you at your prenatal study visits, and after delivery, we will collect a biopsy of your placenta and a blood sample from the umbilical cord. Study visits may include a fasting blood draw, taking body composition measurements via BOD POD*and skin fold thickness, and surveys that ask about food you eat, your feelings and experiences, and about your infant's behavior and development. During the postnatal visits, we will observe your and your child's behavior.

*BOD POD is a machine that measures air displaced by your body to obtain percent body fat measurement. You will sit inside the BOD POD for approximately 5 minutes. It does not use radiation and is safe in pregnancy.

Visit Type	Gestational Age	Duration of Visit	Details
Visit # 1	20-24 weeks	Up to 2 hours	Prior to the visit, you will be emailed surveys about your health and feelings and experiences. At this visit, we will review the consent form, collect a fasting blood sample, collect other biological samples, and take body composition measurements with the BOD POD. After the visit you will receive three phone calls to ask about your diet.
Visit #2	35-39 weeks	Up to 2 hours	Prior to the visit, you will be emailed surveys about your health and feelings and experiences. At this visit, we will

Visit Schedule

For questions or to schedule a phone screening, please call 503-418-8249 or email PEACH@ohsu.edu

			IRB Approved: 11/26/2018
			collect a fasting blood sample, collect other biological samples, and take body composition measurements with the BOD POD and skin fold thickness, and complete surveys. After the visit you will receive three phone calls to ask about your diet.
Delivery Sample Collection	Delivery	This will not require any of your time.	When you come to the hospital for delivery, we will take placental and cord blood samples after delivery.
4 Postpartum visits	6, 12, 24 and 36 months	Up to 2 hours	Surveys about you and your child's health, nutrition, and development will be e-mailed to you prior to your visit. At your appointment, you will both take part in the child behavioral assessments and we will collect biological samples from you and your child.
<u>Optional</u> First Trimester Blood Draw	10-14 weeks	30 minutes	At this visit, we will review the consent form and collect a fasting blood sample. We may collect other biological samples.
<u>Optional</u> 1 month EEG	1 month postpartum	1 hour	Prior to the visit, you will be emailed surveys about your health and feelings and experiences. At this visit, your child will take part in an EEG, a test that measures electrical activity of the brain. We will also collect biological samples from you and your child.

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Expectations

Participants are expected to do the following while participating:

- Attend visits
- Complete questionnaires and phone interviews

- Stay communicative; it's important to keep your study coordinator in the loop. Please make sure to call or email in advance if you know you won't be able to make a visit.

Study Procedures

- Collect medical information
- Blood draw
- BOD POD
- Mom and infant behavioral surveys and assessments
- Diet history surveys
- Infant nutritional surveys
- Placental measurement and samples
- Umbilical cord blood samples
- Collect your child's growth/health information
- Collect other biological samples from you and your child (saliva, urine, feces, breastmilk, hair, nail clippings)

Basic Eligibility Criteria

This study is seeking women who:

- Are 18-40 years old
- Generally healthy
- Are currently gestational age of 24 weeks or less
- Planning delivery at OHSU

Compensation

Your total compensation could be up to \$550 throughout the whole study. Participants are compensated \$50-\$200 per visit, with the higher amounts reserved for later visits.

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