UCDAVIS FOODS FOR HEALTH INSTITUTE

Infant Microbiome, Nutrition, and Development (Infant MiND) Study

Who is conducting this Study?

This clinical study is led by Dr. Jennifer Smilowitz, Ph.D., at the UC Davis Foods for Health Institute in collaboration with Dr. Lisa Oakes at the UC Davis Center for Mind and Brain. This study has been reviewed and approved by the UC Davis Institutional Review Board.

What is the purpose of the study?

This is a 2-month study aimed at understanding 1) how the infant gut microbiome changes in response to ingesting solid foods, 2) how infant cognition develops in response to ingesting solid foods, and 3) the relationship between infant gut microbiome and infant cognition during the first year of life.

Who can participate?

- > Healthy mothers who are 21-45 years old and gave birth to a single, healthy, term (>37 weeks) infant;
- Predominately breastfed infants who are 5.5 to 7.5 months old and demonstrate readiness for solid food;
- Mothers who plan to continue to breastfeed their infants until 8 months of age or older;
- Participants are eligible if they live in Davis, Woodland, Dixon, Vacaville or Sacramento;
- Healthy infants without medical complications;

Who is NOT eligible to participate?

- Infants who were from a multiple birth;
- > Infants who already have or will consume solid foods before turning 6 months of age;
- Infants who have consumed infant formula on more than 10 days;
- Infants who have consumed probiotics in the past 4 weeks;
- Infants who have taken antibiotics in the past 4 weeks;
- Infants who have consumed iron supplements in the past 4 weeks;
- Infants who have a medical or nutritional need for iron supplements;
- Infants who have poor head control;
- Infants born by cesarean section
- Mothers who smoke or plan to start smoking during the study period;
- Mothers with obesity (BMI > 34.9);

What is expected of me during the study?

This study lasts up to 6 months with the bulk of the study activities occurring within the first 2 months. Over the study period you will be asked to do the following: feed your infant a commonly consumed baby food (organic pears); collect 4 breast milk samples, 1 stool samples from yourself, and 9 stool samples, and 1 saliva sample from your infant. Study personnel will instruct you on how to collect samples and you will be asked to store them in your freezer until a scheduled pick-up. You will be asked to fill out weekly and monthly questionnaires regarding your and your infant's health, diet and environment as well as daily updates on your infant's diet and health for the first month of the study. You will be asked to come to the UC Davis Center for Mind and Brain in Davis on 3 different occasions for infant cognitive and motor assessments and to schedule a total of 5 visits in your own home with study personnel.

Will I be compensated for participation?

Participants may receive up to \$285 in gift cards.

For more information please contact the Human Studies Coordinator, Annie Meier (888) 217-5355 or email at: infantmind.ucdavis@gmail.com. Visit our website at: <u>infantmind.ucdavis.edu</u> Updated: 01/01/2019