JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title: Prenatal indicators of child self-regulation
Principal Investigator: Janet DiPietro, Ph.D.
Student Investigator: Kristin Voegtline, Ph.D.
IRB No.: 00005788
PI Version Date: 08.22.2014

What you should know about this study
- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project
The purpose of this research study is to help us understand how naturally occurring hormones during pregnancy that we previously measured in your saliva influences children’s development and behavior in early childhood as well as their own hormone levels.

Why you are asked to participate:
You have been asked to participate in this study because you previously participated in the study while you were pregnant and you may have also come into our lab with your infant at 6 months of age.

Procedures:
For comfort and convenience, this study visit will take place in your home. If you agree to be in this study, you and your child will be asked to participate in several tasks. These tasks are meant to understand how your child focuses their attention and manages emotions. The first task will be for you and your child to play as you normally would at home, while we video-record how you play. We will then take a saliva sample from your child similar to how we collected saliva during your pregnancy and with your infant, using oral swabs. We will use your child’s saliva samples to measure hormones related to development, such as testosterone, and stress, such as cortisol. After, you will be asked to complete a set of questionnaires in a separate room on your stress and well-being, and your child’s behavior.
During this time, your child will begin by ranking a set of toys from most to least favorite. Next, we will scan an image of your child’s left and right hand. We do this to measure the ratio of the index to the ring finger length, which may be related to hormone exposure during pregnancy. Then your child will use a touch screen computer to play a set of games guided by a research assistant: bubble popping, picture memory, tapping directional arrows, and matching. When these games are complete, we will collect a second saliva sample from your child. Then we will move on to two additional tasks that will be potentially frustrating or disappointing. We will video-record your child’s response to these last two tasks. First, your child will be given one treat of their choosing (a marshmallow or M&M) and a bell. They will be told that the experimenter will be back in a few minutes. If they can wait until their return to eat it, they will be given a second treat. If not, they can ring the bell at any time to indicate that they want to eat the first treat. Second, your child will be given a disappointing toy (i.e., the least favorite toy selected earlier) as a gift. After a minute has elapsed, the research assistant will explain to your child that they made a mistake and give them their selected favorite toy. You will then rejoin your child, and we will collect two more saliva samples from your child as we wrap-up the visit. Prior to the third saliva sample we will ask your child to rinse their mouth with water since they recently ate treats. We collect several saliva samples during the course of the visit to determine how your child’s hormone levels change across the tasks. The visit will take no more than 1 ½ hours.

Also, at the end of the visit we will leave you with a pre-paid return addressed envelope that we would like you to pass along to your child’s teacher to complete and send back to us. It contains a disclosure form explaining that you and your child are part of a research study, two brief questionnaires, and a $5 Starbucks gift card as a thank you to your child’s teacher.

Risks/discomforts:
There are minimal risks for this study. Your child may become frustrated or experience disappointment with some of the tasks. You are free to skip any questions you are not comfortable answering about yourself or your child.

Benefits:
There are no direct benefits to you or your child for participating.

Payment:
For taking the time and energy to participate in this study, you will be given a $40 gift card to Target. Your child will also receive a small gift.
Protecting data confidentiality:
You will be assigned the same identification number that was given to you during the previous study. Personal identifying information will be removed from all documents. All documents and videotapes will be stored in a locked cabinet that is only accessible to the primary and student investigators. We will keep a separate list of identification numbers and contact information if it is necessary to follow-up. Scanned images of your child’s hand will be destroyed following measurement of the digit ratio. Video data will only be viewed by research personnel and will be destroyed after the completion of the five year grant.

Protecting child welfare:
Research personnel are required to notify the local office of the Maryland Department of Human Resources about suspected cases of child abuse or neglect.

Who do I call if I have questions or problems?

- Call investigator, Kristin Voegtline, at (814-769-1574) or by email at kvoegt1@jhu.edu if you have questions or complaints.

- Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

  Address: Johns Hopkins Bloomberg School of Public Health
  615 N. Wolfe Street, Suite E1100
  Baltimore, MD 21205
  Telephone: 410-955-3193
  Toll Free: 1-888-262-3242
  Fax: 410-502-0584
  E-mail: JHSPH.irboffice@jhu.edu
What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study’s purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Print name of Adult Participant ___________________________ Signature of Adult Participant ________________ Date ____________

Assent Statement

Print name of child participant ___________________________

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

Print name of Parent/Legal Guardian ___________________________ Signature of Parent/Legal Guardian ________________ Date ____________

Print name of Person Obtaining Consent ___________________________ Signature of Person Obtaining Consent ________________ Date ____________

Give one copy to the participant and keep one copy in study records