We are asking you to participate in a research study. This form is designed to give you information about this study. We will describe this study to you and answer any of your questions.

Project Title: Effects of iron deficiency on infant cognitive development

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What the study is about
We are interested in learning about the effect of iron status on memory performance in infants aged 4 to 7 months, and whether iron deficiency negatively affects infant memory performance. We are also interested in learning about mother and infant experiences in this study so that we can design a larger, longitudinal study to investigate the effects of iron deficiency on memory development in infants. We are therefore asking mothers of healthy infants to participate in this study.

What we will ask you to do
If you agree to participate you will be asked to participate for three days. On the first day, you will be asked to answer questions about your infant’s medical history, feeding and sleeping habits, and about your day-to-day interactions with your infant. We will take notes about your interactions with your infant here in the lab today, and we ask that you simply interact with your infant as you normally do. Additionally, we will measure your infant’s length, weight, and head circumference. A trained phlebotomist from Cayuga Medical Center will take a small (2 milliliter) blood sample from your infant’s heel. The blood sample will be analyzed to give us information about your infant’s iron status, and samples will be destroyed when the study is complete. This entire process will take place in the Human Metabolic Research Unit at Cornell University, and will require no longer than 2 hours of your time. We will pay the transportation or parking costs for the visit.
At your convenience, we will schedule another time for you to come with your infant to the Robertson Infant Lab in the Department of Human Development at Cornell University. Your infant’s eye movements will be video recorded without using bright lights, while we show him/her pictures of female faces on a screen. In order to assess what your infant is paying attention to and remembers during the study, we will record some of the small electrical signals produced by the brain that can be detected on the scalp (EEG). Your infant will wear a cap made of a stretchy material with small sponges in it. Each recording site on the cap holds a small sponge filled that is soaked with a water-soluble solution. This solution is hypoallergenic, and can be quickly removed with a damp washcloth. The recording equipment is constructed to prevent the possibility of electrical shock. Between uses the cap is washed and disinfected. We will also measure your infant’s heart rate with three electrodes. Each electrode location on your infants torso will first be wiped clean with an alcohol swab, and then the electrodes will be placed according to standard recording methods. The electrodes are reusable, and will be held in place by adhesive disks that keep the electrode connected to the skin. The disks are made to be gentle on skin to minimize discomfort during removal. These disks are disposable and we will use new disks for your infant. The electrodes are cleaned and disinfected between uses. This entire process will require no longer than 90 minutes of your time, and we will pay the transportation or parking costs for the visit.

At your convenience, we will schedule a second time for you to come with your infant to the Robertson Infant Lab. During this visit, your infant will again be shown pictures of female faces on a screen, and his/her eye movements will again be video recorded. In order to assess what your infant is paying attention to and remembers during the study, we will measure the amount of time he/she spends looking at each of the pictures. Finally, we will ask you to answer a few questions about your experiences participating in the study. We will use this information to design a larger, longitudinal study to examine the effects of iron deficiency on the development of memory in infants. This entire process will require no longer than 60 minutes of your time, and we will pay the transportation or parking costs for the visit.

Risks and discomforts
Mild discomfort and bruising at the site of the needle stick may occur as a result of blood sampling. A trained phlebotomist will collect blood samples Cornell University's Human Metabolic Research Unit. You will be present for the blood draw, and may comfort your infant as needed.

Although rare, minor skin irritation may occur due to the electrolyte that will be used for the EEG recording. The electrolyte is water-soluble and will be removed with water and a clean cloth if there are any signs of irritation, and testing will be stopped.

Psychosocial risks are unlikely, but some of questions (e.g. breastfeeding behaviors) could make you uncomfortable. Your answers will be kept strictly confidential, and will not be used for any purposes other than the research purposes of this study. You are not required to answer any questions, and not answering a question will not affect your or your infant’s ability to participate in the study.

We anticipate no other risks, other than those involved in day-to-day life.

Benefits
Although there are no direct benefits for you or your infant, others may benefit from the knowledge gained in this study.

**Cost of participating**
The there will be no costs to you for participating in this study.

**Payment for participation**
You will receive a $10 gift card after participating in the first day of the study, a $15 gift card after participating in the second day of the study, and a piece of clothing for your infant after participating in the third day of the study.

**Audio/Video Recording**
Your infant’s eye movements will be video recorded without using bright lights, while we show him/her pictures of female faces on a screen. The recording will allow us to assess which pictures your infants spends the most time looking at, which will give us necessary information about his/her attention and memory. The recordings will be kept indefinitely for analysis and any necessary follow-up.

We would like to request your permission to use clips from the video recording for educational purposes, to illustrate the study’s methods to students and researchers. If your infant’s video recording is used, his or her name will not be associated with it. By giving your consent you give up the right to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings. Additionally, you recognize that neither you nor your infant will receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings. Your consent is completely voluntary and withholding your consent will not affect your current or future relationship with the researchers or the university.

**Please sign below if you are willing to have video clips of your infant used for educational purposes (including demonstrations or presentations that may be open to the public), as denoted above. You may still participate in this study if you are not willing to have the video clips used for educational purposes.**

☐ I do not want video recordings of my infant to be used for any purpose other than the research goals of this study.

☐ I am willing to have video recordings of my infant used for educational purposes, as denoted above:

Signed: ________________________________

Date: ________________________________

**Photography**
We would like to request your permission to take photographs of your infant for educational purposes, to illustrate the study’s methods to students, researchers, and future study participants. If your infant’s photograph is used, his or her name will not be associated with it. By giving your consent you give up the right to inspect or approve the finished product or printed/published matter that uses the images
or versions of the images. Additionally, you recognize that neither you nor your infant will receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images. Your consent is completely voluntary and withholding your consent will not affect your current or future relationship with the researchers or the university.

Please sign below if you are willing to have photographs of your infant used for educational purposes (including demonstrations or presentations that may be open to the public), as denoted above. You may still participate in this study if you are not willing to have the photographs used for educational purposes.

☐ I do not want photographs of my infant to be used for any purpose other than the research goals of this study.
☐ I am willing to have photographs of my infant used for educational purposes, as denoted above:

Signed: ________________________________

Date: ________________________________

Abnormal Test Results
In the event that we get back any abnormal results from the blood analysis for iron indicators, we will inform you about these results within 60 days and recommend you contact your private medical provider for follow-up. Please be advised that as researchers, we are not trained to diagnose or treat medical conditions. You or your insurance company will be responsible for payment of any treatment of medical conditions.

If you are injured by this research
In the event that any research-related activities result in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Cornell University. If you think that you have suffered a research-related injury, contact Julie E. Hammons right away at (607) 254-6403.

Privacy/Confidentiality
The data obtained in this study will be kept confidential. All data and records will be labeled with a number code to increase confidentiality and kept in a locked office space at Cornell University, separate from identifying information. Information not on paper will be stored on a password-protected external hard drive, which will also be locked filing cabinet, within a locked office space at Cornell University. Only the principal investigator and faculty advisor will have the key and password. All data and records obtained by members of the research team will be used solely for research purposes.

If you communicate with a member of the research team by email, please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.
Taking part is voluntary
Participation in this study is completely voluntary. We will stop at any time if you wish us to do so. We will also stop if your infant becomes sleepy, fussy, or in any way uncomfortable. Not participating or stopping before the session is finished will not affect your current or future relationship with the researchers or the university.

Withdrawal by investigator, physician, or sponsor
The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication/treatment, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

If you have questions
The main researcher conducting this study is Julie E. Hammons, a graduate student at Cornell University in the Division of Nutritional Sciences. Please ask any questions you have now. If you have questions later, you may contact Julie E. Hammons at jeh293@cornell.edu or at (607) 254-6403. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-5138 or access their website at http://www.irb.cornell.edu. You may also report your concerns or complaints anonymously through Ethicspoint online at www.hotline.cornell.edu or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

Statement of Consent
I have read the above information, and have received answers to any questions I asked. I consent to take part in the study, and give permission for my infant to participate.

Parent’s Name (printed)  
Infant’s Name

Parent’s Signature  
Date

Name of person obtaining consent  
Date

Signature of person obtaining consent  
Date

This consent form will be kept by the researcher for at least five years beyond the end of the study.