Parental Permission for Research Involving Child Study Participants

We are asking you to give permission for your child to participate in a research study. This form is designed to give you information about this study. The Principal Investigator or representative will describe this study to you and answer any of your questions.

Project Title:
Effect of maternal choline intake on cognitive performance in children: A follow-up study

Investigators:
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What the study is about:
We are asking your permission for your child to take part in this study because you have a child who is 7 years of age. We are interested in studying whether increased maternal intake of choline during pregnancy improves her child’s cognitive abilities at age 7.

Choline, a nutrient found in the diet (i.e., eggs, nuts, and beef), was recognized as a required nutrient for humans in 1998. The recommended dietary intake level for pregnant women is 450 mg/d. However, at present, it is not known whether this amount is optimal for pregnant women. Previously, we assessed the effect of choline intake during pregnancy on cognitive function in infants.

We would like to assess cognitive function in children at age 7. There is evidence from animal studies that increased intake of choline by the mother during pregnancy may have long lasting beneficial effects on the memory and attention of her offspring. However, it is not known whether long-lasting cognitive benefits are also seen in humans. This follow-up study seeks to assess the effect of maternal choline intake during pregnancy and lactation on learning, attention, and memory in children at 7 years of age. This study will provide extremely important information to determine optimal choline intake during pregnancy and lactation.

What we will ask you to do:
If you give permission for your child to participate your child will be asked to participate in two sessions on consecutive days. Each session will require approximately 90 minutes. We’ll also ask you to answer questions about your child’s health history and day-to-day behavior. The sessions will take place in our laboratory at Cornell University, which is a quiet, kid friendly room.

Cognitive Assessment
We would like to perform cognitive tests to assess your child’s attention, memory, and overall cognition. Some of the tests require your child to use a computer. For example, in one test we will ask your child to remember faces they saw on a computer screen by pressing a button. Other tasks will involve objects.
(e.g. using plastic shapes to re-create a design) or conversation with a researcher (e.g. we might ask your son/daughter to describe the differences between two objects). These tests are non-invasive. Each task is approximately 5-10 minutes and will total 90 minutes per visit, including time for breaks in between tests.

**Questionnaires**
We will ask you to complete four questionnaires to give us more information about your child’s health history, behavior, and your day-to-day interactions with your child. For example, the behavior questionnaire might ask you to respond to the statement “My child is easily soothed when angry” with one of these four responses: 1) Never 2) Sometimes 3) Often 4) Almost always.

The questionnaires should take 10-20 minutes each to complete, totaling less than one hour per visit. You may complete the questionnaires while your child completes the cognitive tests.

**Saliva Sample**
We will collect saliva samples from your child to measure cortisol levels, which will tell us about the body’s response to daily stress. At the first study visit, we’ll ask your child to spit into a small container before, during, and after the cognitive testing. We also need to get samples across different times of day to measure the usual pattern of your child’s cortisol levels. On two days, we’ll ask you to collect additional saliva samples immediately after he/she wakes in the morning, 30 minutes after waking, right after school, and before he/she goes to bed. We’ll provide you with instructions and supplies for collecting the saliva samples and returning the samples to our lab.

**Risks and discomforts**
We foresee minimal risks to you or your child as part of your participation in this study. If you give permission for your child to participate, he/she will have to agree to participate as well and he/she can request a break or to stop the testing at any time. You are not required to answer any part of the questionnaires, and not answering a question will not affect your or your child’s ability to participate in the study. Your child’s responses on the cognitive tests, and your answers on the questionnaires will be kept strictly confidential, and will not be used for any purposes other than the research purposes of this 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 child, others may benefit from the knowledge gained in this study.

**Compensation**
You will receive $50 after participating in the first day of the study, and $50 after participating in the second day of the study.
Audio/Video Recording
Your child will be video recorded during some of the tests, so we can assess his/her emotional responses to the tests. 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 child’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 child 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 child 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 child to be used for any purpose other than the research goals of this study.

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

Signed: ___________________________ Dated: ________________

Photography
We would like to request your permission to take photographs of your child for educational purposes, to illustrate the study’s methods to students, researchers, and future study participants. If your child’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 child 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 child 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 child to be used for any purpose other than the research goals of this study.

• I am willing to have photographs of my child used for educational purposes, as denoted above:

Signed: ___________________________ Dated: ________________
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 our study manager right away at 607-431-8292.

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 study investigators will have the key and password. All data and records obtained by members of the research team will be used solely for research purposes.

Taking part is voluntary
Participation in this study is completely voluntary. We will stop at any time if you or your child wish us to do so. 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 Professor Barbara Strupp. Please ask any questions you have now. If you have questions later, you may contact our study managers at cholkids@cornell.edu or at (607) 288-2861. You can also contact Barbara Strupp at bjs13@cornell.edu or at (607) 255-2694. 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.

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 child to participate.

_________________________________________    ________________________________
Parent’s Name (printed)                         Child’s Name (printed)

_________________________________________    ________________________________
Signature                                        Date

_________________________________________
Name of Person Obtaining Consent

_________________________________________    ________________________________
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.