Cover Page for Informed Consent – English version

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University of Kansas Medical Center
RESEARCH CONSENT FORM

Growth and Adiposity in Newborns: The Influence of Prenatal DHA Supplementation
Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

You are being asked to consider a research study for your child. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time about allowing your child to participate. There will be no penalty to your child if you decide not to let them participate, or if they start the study and you decide to stop early. Either way, they can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what your child will have to do if they are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about your child participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Holly Hull as the researcher. About 400 people will be in the study at KUMC.

Why is my child being asked to take part in this study?
Your child is being asked to take part in this study because you were a participant in the ADORE prenatal DHA supplementation study.

Why is this study being done?
Over 50% of women gain excessive weight during pregnancy, which is associated with greater infant body fat at birth, leading to greater childhood body fat. Children with greater body fat are more likely to be obese as adults and are at more risk of obesity-related diseases. Because of the high rate of childhood obesity, we need to know more about how nutrients in food affect how the body gains fat.

Initial research suggests that docosahexaenoic acid (DHA) could be one of those nutrients. Because it's important for early nervous system and brain development, it has recently been added to many prenatal supplements. Increased exposure to DHA during pregnancy may also decrease the amount of fat mass. Research has associated greater DHA levels in pregnancy with lower body fat in children 3-7 years old, and lower fat around the organs in children 5-7 years old. Fat around the organs in adults is linked to greater risk of problems with the heart, blood vessels, and how the body processes energy.

This study is researching whether taking a supplement called DHA during pregnancy can promote a favorable body fat in infants from birth to 24 months. Additionally, we want to determine if there is a difference in this effect for infants whose mothers gained a good amount of weight compared to those whose mothers gained too much weight during pregnancy. We hope to learn how DHA supplements during pregnancy affect how much fat a child has and where it is located.

What is being tested in this study?
By doing this study, researchers hope to learn if taking a DHA supplement during pregnancy can promote a favorable body fat in infants from birth to 24 months, and if excessive or appropriate weight gain during pregnancy impacts this result.

How long will my child be in the study?
Your child's participation will last approximately 2 years.

What will my child be asked to do?
You and your child will be asked to come to the clinic 4 times during this study. Your child will be recruited when you are between 36 to 40 weeks of pregnancy, and will have the first study visit 2 weeks after delivery. If you are not able to enroll at the 2-week time point, you may enroll prior to any of the other study visits. You will be asked to read and sign this consent form before any tests or procedures can be completed. Table 1 describes study activities at visits 1 through 4.

Table 1. An outline of study visits and procedures.

Study procedure	**Visit 1 (2 wks)**	**Visit 2 (6 months)**	**Visit 3 (12 months)**	**Visit 4 (24 months)**
Enrollment & Consent	**Prior to first study visit**			
Anthropometry & skinfolds	•	•	•	•
DXA scan	•	•	•	•
Diet recall	•	•	•	•
Questionnaires	•	•	•	•
Pea Pod **(Optional)**	•	•		

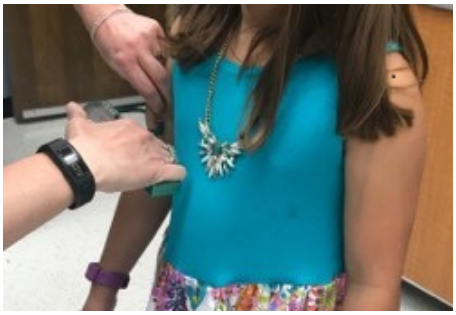
<u>Enrollment (at Visit 1)</u>
The following procedures will occur:

- The study will be explained to you. If you decide to participate, you will be asked to read and sign this consent form before any tests or procedures can be completed. You will be given a copy of the signed informed consent.
- We will review your health history, including your medical and obstetric history, pre-pregnancy weight, income, education, and smoking history that you reported as part of the original pregnancy study.

Visits 1, 2, 3, and 4 (2 weeks, and 6, 12, and 24 months after delivery)
You will be asked to bring your child with you to these visits.
These visits will occur at the main campus of KU Medical Center.
Visits will last approximately 1 hour to 2 hours depending on the time point or visit.

The following procedures will occur:

- You will be asked to complete questionnaires about your child's diet. The questionnaires will ask you about the types and amounts of foods your child eats. You will also be asked about your child's health, and if he/she has been sick.
- At these visits, measurements of your child will be taken to assess his/her growth.
- Your child's length, weight, and head circumference will be measured.
- Your child's skin fold measurements will be taken by compressing the skin and measuring the thickness with an instrument called calipers. Measurements will be taken on the arm, back, hip, thigh, side, and abdomen. This is what a skin fold test looks like:



- Your child's body composition will be measured with a DXA scan. A DXA is a type of x-ray used to measure bone strength. During this test, your child will lie flat on the table and x-ray pictures will measure how much fat and muscle are present. We will attempt to complete the scan while your child is sleeping. If your child is not sleeping, we will coach them to remain still. You will be able to monitor your child during the scan. The scan will last about 3-5 minutes. If your child moves during the scan it may need to be redone, but no more than 8 scans will be given over the duration of the study. This is what a DXA scan looks like:

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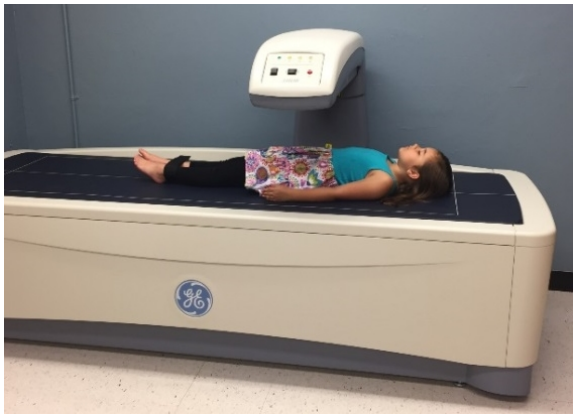

Medical Records
Medical records will be requested upon completion of study or ROI form expiration date. We will record the illnesses your child had, how long they lasted and how they were treated.

What are the possible risks or discomforts?
The study intervention may cause side effects or other problems. However, you should tell the research team about anything that is bothering your child or any changes in your child's health since the last visit. The researchers may be able to take steps to reduce side effects. Your child may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.

Body Composition Testing
The DXA scans for body composition will expose your child to radiation. This radiation exposure is not needed for your child's medical care. Everyone is exposed to radiation every day. This radiation comes from the sun and the earth. The amount of radiation exposure from each DXA scan is about the same amount that your child receives from 2-3 hours of natural background radiation. Children are more likely than adults to be harmed from the exposure because a large amount of their tissues are still growing and changing. The risk of harm to your child from this radiation exposure is low.

Skin Fold Measurements
Your child may feel a pinch when the calipers are used to measure their skinfolds. They may cry during the procedure.

Questionnaires
There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time, you may skip a question or stop answering questions altogether.

Possibility of Unknown Risks
There may be other risks of the study that are not yet known.

Are there benefits to being in this study?
Your child may or may not benefit from this study. Researchers hope that the information learned from this study will be useful to make recommendations for DHA intake during pregnancy that may improve growth and body composition outcomes in children.

Will it cost anything to be in the study?
The study will pay for all study-related medical services provided during this study. These services include the study visits, study-related tests and procedures such as the as listed in this consent form.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments for your pregnancy or other health issues are billable to you

or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Will my child get paid to participate in the study?
If you complete all study visits, you will receive up to $500. You will receive $125 for each visit (1, 2, 3, and 4). If your participation in this study ends early, you will be paid only for the visits you have completed. Additionally, if a DXA scan is not acquired during any study visit, the scan may be rescheduled and participants would receive an additional $50 incentive for returning at a later date.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one will know where you spent the money.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

If you are to move away during the study, reimbursement for travel expenses, flight and hotel may be available. All reimbursement will need to be pre-approved by the study team. You will be asked to keep your receipts in order to receive reimbursement. The study team will work with you to schedule your flight, hotel room and transportation.

Will the researchers get paid for doing the study?
The investigator and the KUMC Research Institute, Inc. will receive payment from the source, NIDDK, for conducting this study. Payments will be used for research purposes only.

Dr. Carlson (co-investigator) serves as a consultant for DSM Nutritional Products. DSM provided the capsules for the parent study. Dr. Carlson received payment from the company for these activities. Two committees at KUMC have independently reviewed this project and will continue to watch it. Their goal is to minimize any influence that the financial interests may have on the conduct of the study. However, you should make your own decision about whether these financial interests affect your decision to participate. If you would like more information, please ask the person obtaining informed consent from you. If you have additional questions, you may also contact the Office of Compliance at (913) 588-1288 or toll-free 1-877-588-5757 and TDD (913) 588-7963.

What happens if my child gets hurt or sick during the study?
If your child has a serious side effect or other problem during this study, you should immediately contact Dr. Holly Hull at 913-588-5358. If it is after 5:00 p.m., a holiday or a weekend, you should call 913-588-5000 and ask for the pediatrics attending physician on call. Please tell the physician that you are in this research study. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

Does my child have to be in the study?
Being in research is voluntary. You can choose whether or not you want your child to participate. Even if you decide not to join the study, you or your child can still come to KUMC for services and treatment.

How will my child's privacy be protected?
The researchers will protect your child's information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your child's study records. Your child's health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your child's health information. If you decide not to sign the form, your child cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your child's medical record. Your child may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your child's health information will be used at KUMC by Dr. Hull, members of the research team, The University of Kansas Hospital Medical Record Department, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Hull and the research team permission to share

information about your child with persons or groups outside KUMC. Your child's information will be shared with U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for audit purposes. The purpose for using and sharing your child's information is to make sure the study is done properly and to evaluate the safety and effectiveness of the intervention.

If you are co-enrolled in both this study and the ADORE cognitive study, you give Dr. Holly Hull and her research team permission to share information about your child between the two studies. If you are not enrolled in the ADORE cognitive study, your information will not be shared.

The HIPAA privacy law may not apply to everyone who receives your child's health information. Your child's information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your child's information from improper use.

Your permission to use and share your child's health information will not expire unless you cancel it. Any research information that is placed in your child's medical record will be kept indefinitely.

While your child is participating in this study, you may see and copy any study information that is placed in your child's KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your child's name will not be used in any publication or presentation about the study.

Can my child stop being in the study?
Your child may stop being in the study at any time. Your decision for your child to stop will not prevent them from getting treatment or services at KUMC. Your child might be asked to come back for a final study visit.

You have the right to cancel your child's permission for researchers to use your child's health information. If you want to cancel your child's permission, please write to Dr. Holly Hull. The mailing address is Holly Hull, PhD, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your child's health information, your child will be withdrawn from the study. The researchers will stop collecting any additional information about your child unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Could my child's participation be stopped early?

This study might be stopped, without your consent, by the investigator, the sponsor or by the FDA. Your child's participation also might be stopped by the investigator or by the sponsor if it is in your child's best interest or if you or your child do not follow the study requirements.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide your child with any intervention or treatment if the study is stopped early. Your child's physician will decide about future treatment, if it is needed.

Who can I or my child talk to about the study?
Before you sign this form, Dr. Holly Hull or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your child's rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

Dr. Hull or the research team has given you and your child information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that your child may experience during this study.

By signing this form, you say that your child is freely and voluntarily consenting to participate in this research study. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

Date ___/___/___

Child's Name: _____

Child's Age: _____

Parent's Name:_____
(please print)

Parent's Signature:_____

Parent's Name:_____
(please print)

Parent's Signature:_____

Name of Person Obtaining Consent: _____
(please print)

Signature of Person Obtaining Consent:_____

Optional Consents

The following page describes optional portions of the ADORE GAINS study. Participation in each is voluntary. If you decide not to participate, you can still participate in all other parts of the ADORE GAINS study and you can still receive care at the University of Kansas Medical Center. If you decide to participate, your privacy will be maintained like in the main part of the study.

Contact for Future Studies:

Because you took part in this study, in the future we may want to contact you with information about participating in future studies. Do you give your permission for Dr. Holly Hull or staff to contact you regarding your willingness to participate in future research studies?

- ☐ Yes, I agree to be contacted about future research studies.
- ☐ No, I do not want to be contacted about future research studies.

Parent's Signature: _____ Date ___/___/___

Pea Pod – Infant Body Composition (2 weeks and 6 months)

An alternative method to measuring body composition is with a special incubator called the Pea Pod. This method will be used in addition to the DXA scan. The baby is placed on its back in the incubator so that the amount of space (volume) occupied by the infant can be measured to calculate lean mass (muscle) and total body fat. The staff and parent are able to monitor the child during the test through the transparent window. The test takes about 7 minutes from start to finish. Do you give your permission for Dr. Holly Hull or staff to perform this additional measurement on your child?

- ☐ Yes, I agree to allow my child to complete the Pea Pod.
- ☐ No, I do not want my child to complete the Pea Pod.

Parent's Signature: _____ Date ___/___/___