

## UNIVERSITY OF WISCONSIN MADISON

### PARENTAL CONSENT and MINOR ASSENT to take part in research and AUTHORIZATION to use and/or disclose identifiable health information for research

*Title of the research study:* Effect of CLA supplementation on body fat accretion among children who are overweight or at risk of overweight

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#### INVITATION

You and your child are invited to participate in this research study about the effect of a nutritional supplement, called conjugated linoleic acid, on the change in body fat during six months. Healthy 8 to 10 year old children who are overweight or at risk of becoming overweight are invited to participate. Approximately 76 children will participate in this study at the University of Wisconsin Madison.

Participation in this research study is voluntary. It is up to you and your child to decide if you would like to participate. If you and your child decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

#### A. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to find out if taking 2.4 grams per day of conjugated linoleic acid (CLA), a type of fatty acid found in the diet in dairy and beef products, will reduce body fat during growth in 8-10 year old children who are overweight or at risk of becoming overweight.

#### B. WHAT WILL MY CHILD'S PARTICIPATION INVOLVE?

If you and your child decide to participate in this research study, he or she will be asked to take daily CLA or a placebo for six months. Neither you nor the study investigators will know whether your child is taking the CLA or the placebo until the study is over. CLA is a type of dietary fat naturally found in beef and dairy products such as milk and cheese. The placebo will be an identical amount of sunflower oil, a type of vegetable oil. About 27 calories per day will be taken of either the CLA or the placebo. The CLA and the placebo will be mixed into an 8 ounce chocolate milk.

During the six month study, you and your child will be asked to complete a total of six visits. There will be two long visits at the beginning and end of the study, and two shorter visits in the middle. All of the visits combined will require a total of about 12 hours. During these visits, you will fill out between one and four brief questionnaires for a total of 15 questionnaires during the six months. We will also record personal information including your email, phone number, and mailing address. Each visit is described below, including the type of questionnaire we will ask you to complete at each visit.

- **Visit 1. When:** Start of the study. Visit 1 must be scheduled in the morning before breakfast and after a 12 hour overnight fast where only water is to be consumed. **Where:** UWHC General Clinical Research Center. **How long:** about 2.5 hours. **What:** During this visit, we will measure your child's height and weight to confirm that he or she is eligible. Eligible children will be between the 85<sup>th</sup> and 98<sup>th</sup> percentile of weight based on their height, gender, and age. If your child is eligible based on their weight and height, they will then be seen by the study physician to ensure that they are healthy to participate. Next,

a blood sample will be drawn to measure glucose (sugar in the blood), insulin (a hormone in the blood), blood lipids (cholesterol and fat in the blood) and liver enzymes (proteins in the blood made by the liver). Your child will then complete a sugar tolerance test, which measures the body's response to a sugary drink. A second blood draw for insulin and glucose will be done 2 hours after your child drinks the sugary beverage. The total amount of blood drawn during this visit will be about one teaspoon. During this visit, you will also meet with a dietitian to learn strategies for healthy eating. At the end of this visit, your child will taste a sample of the chocolate milk placebo to make sure that they will like to drink it every day during the study. **Three questionnaires to be completed at Visit 1:** Your child's nutrition, physical activity, and symptoms over the past two months.

- **Visit 2. When:** Start of the study. Visit 2 will be scheduled during the after school hours. **Where:** UWHC Research Park Clinic. **How long:** about 3 hours. **What:** During this visit your child's body fat and muscle will be measured with three tests. There are three body composition tests to measure the amount of the body that is water, the amount of the body that is mineral, and the density of the body. For the first test, your child will spit into a tube, and then drink a dose of water which contains a naturally occurring form of hydrogen (a substance that makes up water). Your child will spit into a tube again after 2 hours and again after 3 hours and we will measure the amount of hydrogen in the spit. This test tells us how much of the body is made up of water. For the second test, your child will lie on a table while an x-ray scans their body for 5-10 minutes. This test will tell us how much of the body is made up of mineral. For the third test, a device called the Bod Pod will measure your child's body volume (how much space your child takes up). For this test, your child will sit inside of an egg-shaped booth that has a large window for 5-10 minutes. He or she will be asked to breathe through a tube for part of the test. Your child will be allowed to exit the Bod Pod at any time during the test if they are afraid. We will ask you to stand nearby where your child can see you during the test. Because of this test, if your child is claustrophobic (afraid of small spaces) we will ask that you and your child do not participate in this research study. After this visit, you and your child will be provided with a \$25 gift card and a two month supply of chocolate milk containing the placebo or CLA. You may be asked to pick up your chocolate milk at the Nutritional Sciences Building on the UW Campus.
- **Visit 3. When:** After 2 months. Visit 3 will be scheduled in the morning before breakfast and after a 12 hour fast where only water is to be consumed. **Where:** UWHC General Clinical Research Center. **How long:** about 30 minutes. **What:** At this visit, a blood sample will be drawn for the same markers as in Visit 1. This will be done to confirm that your child's blood values are still within normal ranges. The total amount of blood drawn during this visit will be about a half of a teaspoon. We will also measure your child's height and weight. After this visit, you and your child will be provided with a second \$25 gift card and another two month supply of chocolate milk containing the placebo or CLA. You may be asked to pick up your chocolate milk at the Nutritional Sciences Building on the UW Campus. **Four questionnaires to be completed at Visit 3:** Your child's nutrition, physical activity, symptoms, and the amount of chocolate milk your child drank over the past two months.
- **Visit 4. When:** After 4 months. **Where:** UWHC General Clinical Research Center. **How long:** about 30 minutes. **What:** At this visit, will measure your child's height and weight. After this visit, you and your child will be provided with a third \$25 gift card and another two month supply of chocolate milk containing the placebo or CLA. You may be asked to pick up your chocolate milk at the Nutritional Sciences Building on the UW Campus. **Four questionnaires at Visit 4:** Your child's nutrition, physical activity, symptoms, and the amount of chocolate milk your child drank over the past two months.
- **Visit 5. When:** After six months. **Where:** UWHC General Clinical Research Center. **How long:** about 2.5 hours. **What:** This visit will be similar to Visit 1, except that you and your child will not need to meet with the study physician or the nutritionist. **Four questionnaires at Visit 5:** Your child's nutrition, physical activity, symptoms, and the amount of chocolate milk your child drank over the past two months.

- **Visit 6. When:** After six months. **Where:** UWHC Research Park Clinic. **How long:** about 3 hours. **What:** This visit will be similar to Visit 2. This will be the last study visit.

### **C. ARE THERE ANY BENEFITS?**

You and your child are not expected to benefit directly from participating in this study. You will learn about your child's body fat and muscle, blood chemistry measures, physical activity, and nutrition. Your child's participation in this research study may benefit other children in the future by helping us learn more about whether conjugated linoleic acid reduces body fat during growth in children who are overweight or at risk of becoming overweight.

### **D. WILL I BE PAID?**

You and your child will receive four Target gift cards in the amount of \$25 each for participating in this study after Visit 2 (beginning of the study), Visit 3 (after two months), Visit 4 (after four months), and Visit 6 (end of the study).

### **E. ARE THERE ANY SIDE EFFECTS OR RISKS?**

- **Blood sampling:** Blood draws can cause pain, redness, swelling, bruising, fainting, and on rare occasions, infection. The redness, swelling and bruising should go away in a few days. Blood will be drawn by a nurse in the UWHC and sterile procedures will minimize the risk of infection.
- **Body composition tests:** The hydrogen used to measure body water is naturally occurring and does not produce any radiation. The Bod Pod is an egg shaped booth with a large window that your child will sit inside of for 5-10 minutes. The Bod Pod may be problematic for children who are claustrophobic (fear of small spaces) so we will ask you and your child not to participate if your child has claustrophobia. The instrument used to measure body mineral will expose your child to an amount of radiation similar to a chest x-ray.
- **CLA supplement:** There have been many studies on the effect of CLA on body fat in adults (about 19 studies and almost 600 adults). Most of these studies have recorded symptoms reported by the people taking CLA or placebo. No major adverse events have been reported that were thought to be related to the CLA or placebo. People taking CLA in these studies also did not report more minor events than those taking the placebo. The most common minor events with both CLA and placebo groups have been reported to be stomach problems such as diarrhea, abdominal discomfort, and constipation. This may or may not be due to the eating of the CLA and placebo capsules that are often used in adults studies. In the current study, the CLA and placebo oils will be mixed into chocolate milk rather than given in capsule form. Many of the studies of CLA in adults have also taken blood samples and looked at changes in markers such as lipids (cholesterol and fat in the blood), glucose (sugar in the blood), insulin (a hormone in the blood that helps sugar get into cells), and liver enzymes (proteins made by the liver and found in the blood). Some studies have found no changes in these blood tests with CLA, while others have found values to go up or down slightly. In our laboratory at UW-Madison, we studied 3.2 grams per day of CLA in 40 overweight adults for 6 months and found no effect of CLA on blood lipids, glucose, insulin, or liver enzymes. In the current study, we will measure the same markers at the beginning of the trial, after 2 months, and after 6 months.

### **F. HOW WILL MY CHILD'S PRIVACY BE PROTECTED AND WHO WILL USE MY CHILD'S HEALTH INFORMATION?**

Research data will be marked with a code and will not contain you or your child's name or other information that can be used to identify you or your child. There will only be one document that will link your child's name to the code, and this will be stored on a secure network and will be accessible only to the investigators. A paper copy will be stored in a locked office that is also only accessible to the study investigators.

The information collected from you and your child during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. The UW-General Clinical Research Center's Research Subject Advocate and the Data Safety and Monitoring Committee may also review medical records and other information. It may also be shared with others at the UW-Madison. Others at UW-Madison and its affiliates who may need to use your child's health information in the course of this research include:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison

Others outside of UW-Madison and its affiliates will not receive your child's health information in the course of this research. People outside the UW-Madison and its affiliates who receive your child's health information may not be covered by privacy laws and may be able to share your health information with others without your permission. The company sponsor of the study (Lipid Nutrition, B.V) will have access to study related data, but any data that is provided to the sponsor will be marked with a code and will not contain you or your child's name or other information that can be used to identify you or your child.

### **G. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?**

You and your child's permission is voluntary. You and your child do not have to sign this form and may refuse to do so. If you and your child refuse to sign this form, however, you and your child cannot take part in this research study. You and your child may completely withdraw from the study at any time. You and your child also may choose to cease participation or skip any questions that you do not feel comfortable answering. If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from the UW-Madison and its affiliates will not be affected in any way.

### **H. HOW LONG WILL MY PERMISSION TO USE MY CHILD'S HEALTH INFORMATION LAST?**

By signing this form you are giving permission for your child's health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you and your child can no longer actively take part in this research study. You may withdraw your permission at any time by writing to: *Dr. Dale A. Schoeller, Department of Nutritional Sciences, 1415 Linden Drive, Madison, WI 53706.*

### **I. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?**

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Dale A. Schoeller at 608-262-1082.

For information on the rights of research subjects, you may contact the UW Hospital and Clinics Patient Relations Representative at (608) 263-8009.

