CONSENT FORM

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

Study Title: The impact of type 1 diabetes and being overweight on risk of future cardiovascular disease in children.

Principal Investigator: David Fields, Ph.D.
Co-Investigators: Sowmya Krishnan, M.D
Piers Blackett, M.D
Kenneth Copeland, M.D

If you are a parent consenting for your minor child, all references to "you" are applicable to your minor child.

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

Why Have I Been Asked To Participate In This Study?

You have been asked to participate in this study because you are between the ages of 13–18 years old, and either you have type 1 diabetes and or have been diagnosed with having excess body fat. You may also be perfectly healthy and have neither of the conditions listed above but are being asked to participate in the study just to serve as a control for comparison purposes.

Why Is This Study Being Done?

This study is being done to determine if type 1 diabetic children who are overweight have similar body composition (how much fat you have and where you have it on your body), lipid profile (cholesterol level in blood) and vascular function (how healthy your blood vessels are) to children who have diabetes without excessive body fat. You will be screened for eligibility into the study. If found eligible for the study you will have a physical exam done by the doctor which will include checking your sexual maturity. Then you will be given a food recall questionnaire where you will be asked to recall the food you ate in past 24 hours and past 4 days.
The tests involved in this study are commonly used research tools that measure body fat. The tests include dual energy X-ray absorptiometry (DXA); vascular function (Pulse Wave Analysis) and physical activity (step monitor). Also a blood draw will be performed to measure the different kinds of fat in the blood.

participant/parent initials _____

How Many People Will Take Part In The Study?

A total of 80 children will take part in this study.

What Is Involved In The Study?

The study will take place at the General Clinical Research Center (GCRC).

Measurements:
Health status: At the initial visit we will record your age, height, weight, sex, race, medical history, waist size, hip size, family history of diabetes, socioeconomic status, and pubertal status. A doctor will evaluate sexual maturity by examining breast and pubic hair development in girls and pubic hair and private parts in boys. In females who are menstruating, a routine urine pregnancy test will be administered. If you are pregnant you cannot participate in the study. These medical tests take about 20 minutes. We will ask that you come in fasting (not having eaten anything overnight) so that blood can be drawn to measure lipids, blood sugar and insulin levels. All blood can typically be taken with a single needle stick. A total of about 1 teaspoon of blood (5 cc) is necessary for the blood draw.

Body Fat Test: How much fat your body has will be measured by dual energy x-ray absorptiometry (DXA). The DXA test will take approximately 20 minutes. For this you will lie down fully dressed on a padded bed while a scanner moves across your body without touching you.

Pulse Wave Analysis: Your blood pressure, arterial elasticity, and heart rate will be measured. Your radial artery will be felt in the wrist, and a pen mark will be made over that artery. During the test a blood pressure cuff will be inflated briefly. The right hand will be placed in a wrist brace and the pulse wave analysis sensor will be fastened over the pen mark. The test will take about 5 minutes and will be done at the same time and location as the DXA.

Blood sugar test: Blood will be drawn to measure your blood sugar level. Additionally your insulin level, fasting lipid profile and other markers of cholesterol level in the blood will be measured.

Food Recall: You will be asked the foods and drinks you ate over the last twenty four hours and the past 4 days.

Physical activity monitor: At the end of the visit you will be given a physical activity monitor to wear on the ankle during your waking hours. It records the number of step you take in a day and gives us a measure of how physically active you are. We will ask you to wear it for a week's time during the time you are awake.

How long is The Study? The study requires two visits. The first visit will be at the clinic and you will have the medical screening including a history and physical exam.

 participant/parent initials _____

You will be asked to fill a 24 hour food recall and a physical activity questionnaire. You will then be given a step activity monitor to wear for the next 5 days. The next visit will be at GCRC when you will be asked to come in fasting. A urine pregnancy test will be administered. There you will have the blood tests, DXA scan, and the pulse wave analysis. You will return your step activity monitor that day. That visit should not take longer than 5 hours.

What Are The Risks of The Study?

There are minimal risks and discomforts involved during your participation in this research study. All research procedures will be conducted by qualified researchers and medical personnel. The potential risk and discomforts associated with the research study are listed below:

Medical Screening: No risks or discomforts are associated with getting personal medical information, but it may be embarrassing to have some measurements done to see how much body fat you have and to have your sexual maturity assessment done.

Body Fat Test: If you agree to participate in this research, you will receive radiation exposure from a DXA scan (a type of X-ray procedure) that you would not receive if you choose not to participate. The radiation exposure that you will receive from the DXA scan is approximately 0.02% of the amount of radiation exposure that an x-ray technologist is permitted to receive in one year.

Pulse Wave Analysis: You may have discomfort when your blood pressure is being checked.

Blood sugar test: Blood will be drawn. The risks and discomforts of blood drawing include possible soreness, infection, and bruising at the site of needle puncture. Very rarely some people can feel light headed and can faint which though serious is temporary.

Food Recall: No risks or discomforts are associated with giving a record of what you ate the day before, but it may be embarrassing.

Are There Benefits to Taking Part in The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. You will receive information about your body composition (overall body fatness), arterial elasticity (healthiness of your blood vessels) and your blood cholesterol levels. The information from this study may be used in future studies aimed at decreasing cardiac risks in type 1 diabetes and being overweight.

What Other Options Are There?

You may choose to not participate in the study.

participant/parent initials _____

What about Confidentiality?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of his/her protected health information.
There are organizations that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration, and the OUHSC Institutional Review Board.

What Are the Costs?

Transportation will be your only cost. Parking is free.

Will I Be Paid For Participating in This Study?

A 20 dollar gift certificate will be provided to the participant on completion of the study.

What If I Am Injured Or Become Ill While Participating In This Study?

In the case of injury or illness resulting from this study, emergency medical treatment is available. However, you or your insurance company may be expected to pay the usual charge for this treatment. No funds have been set aside by The University of Oklahoma Health Sciences Center, the children's hospital, or the sponsor to compensate you in the event of injury.

What Are My Rights As A Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Refusal to participate will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare or willingness to stay in this study.

You understand that you have the right to access the medical information that has been collected about you as a part of this research study. However, you agree that you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

Whom Do I call if I have Questions or Problems?

If you have questions about the study or have a research–related injury, contact Dr. Soumya Krishnan or David Fields at (405)-271-8001 ext: 43091, 43083

respectively.Other numbers for Dr Krishnan is (405)-488-8745 and for Dr Fields is (405) 325-7358. After office hours and on weekends Dr. Krishnan and Dr Fields may be reached through the switchboard operator at 271-3636 or by paging Dr Krishnan at 647-1343 or Dr Fields at 647-4425.

For questions regarding your rights as a research subject, contact the OUHSC Director, Human Research Participant Protection Program at (405) 271-2045.

Signature:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

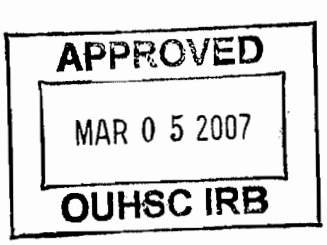
I agree to participate in this study:

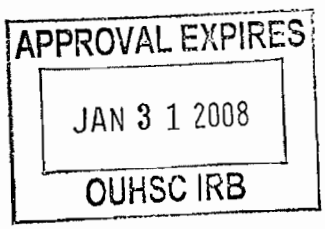
Research Subject: _____
Date: _____

Subject's Printed Name _____

Witness: _____
Date: _____

Person Obtaining Informed Consent: _____
Date: _____





Periodically, researchers may need patients for future studies that you may be able to participate in. By checking below, you are stating it is okay for someone to contact you about discussing participating in a different study. Checking yes below in no way obligates you to participate, only to be contacted regarding possible participation.

I consent to be contacted for future studies on my child / myself / my family:

_____yes **_____no**

Research Subject Signature	Research Subject Printed Name	Date
Parent (Mother) Signature	Parent (Mother) Printed Name	Date
Parent (Father) Signature	Parent (Father) Printed Name	Date
Person Obtaining Informed Consent	Principal Investigator	Date

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IRB Number:

Child Assent Form

Child's Assent (ages 13-17):
The information in the above consent form has been explained to me and I understand it. I agree to participate in this study.

Research Subject Signature	Research Subject Printed Name	Date
Parent (Mother) Signature	Parent (Mother) Printed Name	Date
Parent (Father) Signature	Parent (Father) Printed Name	Date
Person Obtaining Informed Consent Printed Name		Date