The University of Texas Southwestern Medical Center at Dallas

CONSENT TO PARTICIPATE IN RESEARCH
Short Screening Consent

Title of Research: Physical and Metabolic Abnormalities in Lipodystrophy and Dyslipidemias

Sponsor: NIH

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INVITATION: Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

You are invited to participate in this research because either you or your child or your family members have abnormalities of fat cells and metabolism, disorders such as lipodystrophy (either congenital-generalized, familial-partial, or acquired lipodystrophy). Or you have another type of body fat disorder involving problems with fat or sugar metabolism including abnormal blood fats (triglycerides and/or cholesterol) or and other syndromes which may be related, such as premature aging syndromes, obesity or lipomatosis. Also, you may qualify if you have lipodystrophy with HIV. You may also participate as a normal volunteer if you do not show signs of lipodystrophy or body fat abnormalities, in order to serve as part of a comparison group.

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Consent Expires: OCT 18 2010

This study does not offer a treatment or intervention for your condition.

NUMBER OF PARTICIPANTS: The sponsor plans to include 1800 participants in this research.

PURPOSE: You have been asked to undergo a blood test and possibly other tests that will help determine if you have any metabolic disorders such as high blood cholesterol, triglycerides or glucose associated with lipodystrophy (a disease of abnormal body fat distribution), or other types of disorders involving problems with fat or sugar metabolism and other syndromes which may be related, such as premature aging syndromes.

The overall purpose of this research is to examine the physical and metabolic defects associated with lipodystrophy and related syndromes and learn how these develop.

PROCEDURES

Screening: You will be asked questions about your health and health history, there will be questionnaires about your body shape changes and quality of life and you may have a physical exam.

You will have blood tests, and you may have urine tests and measures of height, weight and body fat (anthropometry). These procedures are being done because you are in this research.

Your photographs may also be requested from you or your physician prior to your evaluation here, or we may take photographs while you are here. We use photographs for diagnostic, research and educational purposes. Your photographs may be taken by a professional photographer or a member of Dr. Garg's research team and they may be published in professional scientific journals or medical books but your identity will not be disclosed if any images are published.

How long can I expect to be in this study?

For this study, you may be seen just once, or yearly or every few years or if your body shape or metabolism changes, or at an interval of your choosing. If you have been seen and then months or years later we develop a new study that might help you, we would contact you to see if you would like to participate. Unless you tell us not to contact you in future, or not to contact you after a certain period of time.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers.

Evaluations during the research:

INVESTIGATIONAL PROCEDURES: The tests with their known risks are listed below The nvestigator obtaining this consent from you will check the boxes for the tests you are being asked to undergo. You should read the description of the requested tests and their associated isks. After you understand the tests and risks fully, you will be asked to check in the boxes yes or no if you agree or not for each of the requested tests. Then place your initials where indicated. And you will be asked to sign the consent on the last page.

For children, the blood draw amounts for all the testing will be based on the child's weight and will usually be smaller amounts than those shown for adults.

. **Blood tests,** The risks of donating this blood are minimal but include: (1) a lightheaded or izzy feeling while the blood is being drawn, and a bruise or soreness at the site where the lood was drawn or very rarely infection.

consent to the following blood tests:

The blood tests are for:

	YES	NO	INITIALS
Cholesterol, triglyceride, lipoprotein, and hormone (insulin, leptin, sex hormones, etc.) analysis: 2-4 teaspoons.	☐	☐	☐
SMAC-20 (general blood chemistry screen) and/or CBC: (3 to 4 teaspoons).	☐	☐	☐
Apolipoprotein (proteins related to blood cholesterol) analysis: **(2 tablespoons, or 6 teaspoons**).	☐	☐	☐
Glycosylated hemoglobin A1c (tests for diabetes): (1 teaspoon).	☐	☐	☐
Serum protein electrophoresis and/or Thyroid function tests: (2 teaspoons).	☐	☐	☐

2. **Anthropometry**

a. (Height, weight, and percent of body fat measurements):
In order to determine how much muscle and fat is in your body, we will obtain detailed measurements of height, weight, and skinfold thickness using a tape measure, scale, and calipers (a fat measuring instrument). You will be weighed and measured while wearing minimal clothing, such as underwear and a patient gown.

b. Underwater weighing: This test requires that you put on a bathing suit and get into a tub of lukewarm water. You will be asked to breathe out as much air as you can and go completely under water for a period no longer than 15-20 seconds. While you are underwater , you will hear the investigator knock on the side of the tub, and that will be a signal for you to come up for air. Since it requires breath holding under water, children less than 6 years of age or unable to hold their breath will not be allowed to do this test.

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The risks of anthropometry are only the possible discomfort of holding your breath briefly underwater or the slight pinching feeling of the calipers , which measure skinfold thickness

	YES	NO	INITIALS
ANTHROPOMETRY	☐	☐	☐

3. **OGTT, Oral Glucose Tolerance Test:**

OGTT, Oral glucose tolerance test:: For this test you will have an intravenous (IV) line placed for blood drawing and then receive a sugar drink on an empty stomach in the morning. Blood will be taken from the IV line at 30 minute intervals for 3 hours to check your glucose and insulin response. The total amount of blood drawn for adults will be 45 ml. Which is 3 tablespoons.

The risks of oral glucose tolerance test are the risks of a blood draw or the brief placement of an IV line , bruising, feeling light-headed or dizzy or possible infection, also rarely the sweet drink causes nausea.

OGTT	YES	NO	INITIALS
	☐	☐	☐

4. **Dietary Recall:**

You will be asked about your food intake with a 1 or 3-day food recall or 3 day food record questionnaire, or by interview or phone interview. You maybe called by Dr. Shah or her research assistant to give you additional instructions on completing the food record. This takes up 30 minutes or more of your time. Although careful precautions are taken to protect your privacy, there is an outside chance that an unauthorized person could review your information.

	YES	NO	INITIALS
DIETARY RECALL	☐	☐	☐

POSSIBLE BENEFITS

Benefit to you: A benefit you may receive from having these tests is the knowledge that you either do or do not have a metabolic disorder associated with lipodystrophy or a related syndrome. If we discover that you do have a metabolic disorder, proper therapy to control the condition can be instituted, either through our clinic or by your physician.

Benefit to other people with lipodystrophy, premature aging or related syndromes:

In the future, other people with lipodystrophy, premature aging or other problems related to abnormal fat or glucose metabolism or unusual fat distribution could benefit from the results of this research. Information gained from this research could lead to improved medical care for them. However, your study doctor will not know whether there are benefits to other people with lipodystrophy, premature aging and related syndromes until all of the information obtained from this research has been collected and analyzed.

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COSTS TO YOU: The sponsor will pay the expenses for the test that are done including laboratory work, underwater weight, and oral glucose tolerance test. Expenses related to standard medical care for your lipodystrophy, HIV, premature aging or other syndromes, diabetes, high triglycerides and other metabolic abnormalities are your responsibility (or the responsibility of your insurance provider or government program).

There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

COMPENSATION FOR INJURY: Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Parkland Health & Hospital System,.
You retain your legal rights during your participation in this research.

VOLUNTARY PARTICIPATION IN RESEARCH: You have the right to agree or refuse to participate in this research. If you decide to participate and later change your mind, you are free to discontinue participation in the research at any time.

Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Refusal to participate will not affect your legal rights or the quality of health care that you receive at this center.
Your status as a medical student, fellow, faculty, or staff in the medical center will not be affected in any way.
NEW INFORMATION: Any new information which becomes available during your participation in the research and may affect your health, safety, or willingness to continue in the research will be given to you.

RECORDS OF YOUR PARTICIPATION IN THIS RESEARCH:
You have the right to privacy. Any information about you that is collected for this research will remain confidential as required by law. In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information for Research Purposes," which will contain more specific information about who is authorized to review, use, and/or receive your protected health information for purposes of the study.

YOUR QUESTIONS: Your study doctor is available to answer your questions about this research. The Chairman of the IRB is available to answer questions about your rights as a participant in research or to answer your questions about an injury or other complication resulting from your participation in this research. You may telephone the Chairman of the IRB during regular office hours at 214-648-3060.

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YOU WILL HAVE A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

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Participant's Name (printed)

____ ________________

Participant's Signature Date

____

Legally authorized representative's name (printed)

____ ________________

Legally authorized representative's Signature Date

____

Name (printed) of person obtaining Consent

____ ________________

Signature of person obtaining consent Date

ASSENT OF A MINOR:

I have discussed my participation in this research with my mother or father or legal guardian and my study doctor, and I agree to participate in this research.

____________________________________ ________________

Signature (participants from 10 to 18 years old) Date

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