

CONSENT TO PARTICIPATE IN RESEARCH

TITLE OF RESEARCH: Physical and Metabolic Abnormalities in Lipodystrophy and Dylipidemias

SPONSOR: National Institutes of Health

| INVESTIGATORS: | Telephone No. (office hours) | Telephone No. (other times) |
|-------------------------------|------------------------------|-----------------------------|
| Abhimanyu Garg, M.D. | 214-648-2895 | 214-590-7781 |
| Vinaya Simha, M.D. | 214-648-4773 | 214-590-7781 |
| Peter Snell, Ph.D. | 214-648-9187 | 214-590-7781 |
| Paul Weatherall, M.D. | 214-648-5812 | 214-590-7781 |
| Claudia Quittner, RN | 214-648-9296 | 214-590-7781 |
| David Euhus, M.D. | 214-658-6467 | 214-590-7781 |
| Meena Shah, Ph.D. | 214-648-6874 | 214-590-7781 |
| Dolores Peterson, M.D., Ph.D. | 214-648-3246 | 214-590-7781 |
| Zahid Ahmad, M.D. | 214-648-0548 | 214-590-7781 |
| Ron Hoxworth, M.D, | 214-645-2353 | 214-590-7781 |

INVITATION: You are invited to participate in this research because either you or your family members have adipose tissue 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.

NUMBER OF PARTICIPANTS: Dr. Garg plans to include 1800 participants in this research.

PURPOSE: Dr. Garg wants to learn more about lipodystrophy and other disorders where there are problems with glucose or fat metabolism, including premature aging syndromes. This research is necessary because there is currently not much information available about these problems.

PROCEDURES

For this part of the research, you may be asked for a blood sample, a tissue sample, or both.

Sample of blood: A doctor, nurse, or licensed technician will collect 4-6 teaspoons (20-30ml) of blood by vein one time. We may ask for a second blood sample if the research laboratory cannot process the first sample. The samples will be coded with a unique identifier. This code is based upon the suspected diagnosis and order of presentation to us. This identifier is not kept in your hospital chart.

Cells removed during surgery: If you are planning to have surgery for any reason and we are able to coordinate with your surgeon, we may ask to keep some cells already removed during surgery for this research.



Sample of Tissue: For some subjects a tissue biopsy will be requested. This will involve a skin, muscle, or fat biopsy collected for this research. A skilled physician will perform the procedure.

Adipose Tissue Biopsy (Fat Biopsy):

For this procedure done under sterile conditions, a 2"x 2" area of your skin will be numbed with the anesthetic lidocaine. A small incision (1 ½ inches or less) will be made in the skin, and a small piece of fat (about the size of a marble containing about 5-10 grams of fat) will be removed from under your skin. Cautery may be used to decrease the risk of bruising. The incision will be closed using dissolvable sutures and steri-strips or skin adhesive. Biopsies will be taken from one or two sites, most likely sites are the back of the neck, the abdomen and the upper thigh, if you develop fat accumulations at different sites we may request you allow a biopsy from an alternate or additional site. The tissue obtained by this procedure will be used to determine anatomical and biochemical changes in the fat tissue. Children less than 14 years of age will not have this procedure.

Muscle Biopsy:

If this is a punch biopsy then a small area of skin will be cleaned then numbed with lidocaine, and a tiny incision will be made. A needle will be inserted into your muscle through the incision and a very tiny pea-sized piece of muscle will be withdrawn through the needle (about 200mg). If this is being done as part of a fat biopsy then the procedure is as described for the adipose tissue (fat biopsy) above, the only difference is that the surgeon will also remove a tiny pea-sized piece of muscle through the incision already created to remove the fat. Cautery will be used to minimize bruising. The site will be closed with dissolvable sutures and steri-strips or skin adhesive. The tissue will be used to determine anatomical and biochemical changes in the muscle tissue. Children less than 16 years of age will not have this procedure.

Skin Biopsy:

For this procedure one inch by one-inch area of your skin will be cleaned and numbed with the anesthetic lidocaine. A small round piece of skin about 1/16th inch across will be removed with a punch biopsy instrument. The wound will be closed with steri-strips or skin adhesive and no sutures will be needed. The cells from the skin sample will be grown in culture and anatomical, biochemical and biological changes in these cells will be determined. Children less than 4 years of age will not have this procedure.

For more information about the use of your blood or tissue sample in this research, please read “More Information about This Research” at the end of this consent form.

POSSIBLE RISKS

Questions: We will ask you personal questions. However, you can skip any question that makes you uncomfortable.

Sample of blood: You may experience discomfort, bleeding, and/or bruising. You may feel dizzy or faint. On a rare occasion, an infection could develop at the site where the blood was collected.

Sample of Tissue:

Adipose Tissue Biopsy:

The biopsy site could bleed or form hematoma (collection of blood in tissue), or a bruise. This procedure is done under sterile conditions. There is a minimal risk for infection at the biopsy sites. You could have an allergic reaction to the skin cleanser or to the local anesthetic.



Please tell the study nurse and doctors if you know that you are allergic to betadine, iodine, novocaine or lidocaine. You will have small scars where the incisions are made. You may experience pain during or after the procedure. It is possible that a nerve in your skin might be damaged or cut, causing temporary or permanent numbness in a patch of skin near the incision.

Muscle Biopsy:

The biopsy site is the adipose tissue biopsy site and the risks are the same as above. There may be pressure or pain during or after the procedure, although a local anesthetic agent is used. You could develop bruising or a hematoma (collection of blood in the tissue), the site could bleed. There is a minimal risk for infection at the site. You will have small scars where the incisions are made.

It is possible that a nerve in your skin might be damaged or cut, causing temporary or permanent numbness in a patch of skin near the incision.

Skin Biopsy:

There is a small risk for bleeding, bruising, pain or infection. You will have a tiny scar at the site.

Other risks: The attached document (“**More Information about This Research**”) describes other possible risks related to this type of research.

Unforeseen risks: There could be risks to your participation in this research which Dr. Garg does not know about now.

What to do if you have problems: If you have a medical problem after blood or tissue is collected for this research, Dr. Garg can recommend treatment. Please report the problem to Dr. Garg or Claudia Quittner promptly. Call any one of the telephone numbers listed on the first page of this consent form.

POSSIBLE BENEFITS

To you: Usually there are no personal benefits from participation in this kind of research.

To others: The results of this research may help other people in the future. New information may lead to improvements in medical care for lipodystrophy, premature aging or related syndromes. However, research tests using your sample could possibly fail to produce useful information.

COMMERCIAL DEVELOPMENTS: Research tests using your sample may possibly result in inventions or procedures that have commercial value and are eligible for protection by a patent. Should future commercial developments occur, there are no plans to provide financial compensation to you from the University of Texas Southwestern Medical Center at Dallas or its researchers, and/or other facilities or researchers whose research may benefit from the use of your sample. By agreeing to the use of your sample in research, you are giving your sample with the understanding that there are no plans of providing you acknowledgment, compensation, interest in any commercial value or patent, or interest of any other type. You retain your legal rights during your participation in this research.

PAYMENT TO TAKE PART IN THIS RESEARCH: You will not be paid to participate in this research.



COSTS TO YOU: Collecting a sample of blood or tissue and testing it in a research laboratory will not cost you anything (or your insurance company/government program).

Expenses for routine health check-ups or care for any medical problem 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 a physical injury or any other complication resulting from participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Parkland Health & Hospital System, However, 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 stop at any time.

Your refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled. Your refusal to participate will not affect your legal rights or the quality of health care that you receive at this center.

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 the purposes of this study.

Certificate of Confidentiality: Dr. Garg has obtained a Certificate of Confidentiality from the Federal government. This Certificate will help researchers protect your privacy. However, the Certificate will not protect your privacy if you consent in writing to the release of information about your participation in this research to anyone else.

For more information about a Certificate of Confidentiality, please read "More Information about This Research" at the end of this consent form.

YOUR QUESTIONS: Dr. Garg 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. You may telephone the Chairman of the IRB during regular office hours at 214-648-3060.

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 in this consent form and in the attached document, "More Information about This Research."
- 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.

Participant's name (printed)

Participant's signature and date

Legally authorized representative's name (printed)

Legally authorized representative's signature and date

Name of person obtaining consent (printed)

Signature of person obtaining consent and date

ASSENT OF A MINOR:

I have discussed my participation in this research with my mother or father or legal guardian and [insert name of person obtaining consent], and I agree to participate in this research.

Signature (participants from 10 to 18 years of age) and date

More Information about This Research

What will happen to the samples and information collected for this research? Dr. Garg will compare information about the health of participants with the results of research tests using their DNA, cells or tissue.

What is DNA? DNA means *deoxyribonucleic acid*. DNA is found in almost all of the cells in the body. A gene is that part of DNA which pertains to family traits.

How is DNA obtained? Cells from blood or other body materials are processed in a laboratory that has special equipment that can extract DNA and identify genes.

How long is the DNA kept? Dr. Garg will keep your sample of DNA, cells or tissue in a research laboratory at this medical center until it is all gone, or until he decides to discard the sample. If there is a power failure in the laboratory, and your frozen sample thaws, the sample could become spoiled and useless for future research. If that happens, the sample would be discarded.

If your sample remains stored beyond your lifetime, your sample will be used as described in this document.

May other researchers use your DNA? With your permission, Dr. Garg may give some of your DNA, cells or tissue to other medical scientists who are studying lipodystrophy, premature aging or related syndromes. DNA given to other scientists will not be labeled with your name or any other information that could be linked to you in any way.



Who decides which research scientists may receive samples of your DNA? Dr. Garg asks your permission to use your sample of DNA, cells or tissue as he chooses. The sample will be used only for medical research and will not be sold.

Dr. Garg will decide which researchers at this medical center and at other medical centers may receive samples of your DNA, cells or tissue. Your samples may be used in other research only if the other research has been reviewed and approved by an Institutional Review Board (IRB).

Could your sample be used for other purposes? No one may use your sample or your DNA for purposes other than research without your permission or without the permission of your legally responsible representative and the approval of the IRB at this medical center.

Will the results of research tests be reported to you? Dr. Garg will use samples of your DNA, cells or tissue only for research. The samples will not be used to plan your health care.

Will you be contacted in the future? You may be contacted later for information about your health. Please keep in touch with Dr. Garg and maintain a current address and telephone number on file. Please notify Dr. Garg if your legal name changes.

Dr. Garg or a member of his research team may invite you to participate in other research in the future.

Dr. Garg may recommend that you discuss new information about lipodystrophy, premature aging or a related syndrome with your personal physician.

Any new information which becomes available during your participation in the research and may affect your willingness to continue in the research will be given to you promptly.

Will children be contacted in the future? It is your responsibility to inform a child that samples of his or her DNA, cells or tissue may be kept in a research laboratory at this medical center or possibly other medical centers. The child will not be asked to sign another consent form when he/she reaches age 18.

What are some of the risks that could result from participation in this kind of research?

Stress: You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you.

Personal, sensitive information: If you are not the parent of a child in your family, or if you are the parent of a child in another family, that information could be learned from DNA tests. This kind of information will **not** be reported to you or other family members without your permission.

What is a Certificate of Confidentiality? The Department of Health & Human Services issued a Certificate of Confidentiality for this research. This Certificate enables [insert name of investigator] and other researchers associated with this project to withhold information about your participation. The protection afforded by this Certificate lasts forever. However, the Certificate will not provide protection if you consent in writing to the release of information about your participation in the research to anyone else.



Why is a Certificate of Confidentiality needed? Sensitive information about your health and the health of other members of your family may be collected and studied. The Certificate will help DR. Garg avoid having to release identifying information about you which could expose you and your family to unwanted financial, legal, emotional, and social consequences.

How does the Certificate of Confidentiality protect your privacy? All persons who are employed by or associated with the University of Texas Southwestern Medical Center at Dallas (and its contractors or cooperating agencies) and who have access to information about your participation in this research may withhold your name and other identifying information from all persons not connected with the conduct of that research.

This means that Dr. Garg does not have to identify you as a participant in this research in any Federal, State, or local, civil, criminal, administrative, legislative, or other proceedings.

What are the limitations of the Certificate? This Certificate does not stop you or a member of your family from identifying you as a participant in this research.

For example, if an insurance provider or employer learns about your participation in this research and obtains your consent to receive research information, Dr. Garg may not use the Certificate of Confidentiality to withhold this information.

It is important that you and your family actively protect your own privacy.

If Dr. Garg determines that you could be harmful to yourself or to others, he may report such concerns to proper authorities for your safety or the safety of others. If the investigators suspect child, elder or disabled person's abuse, they will report such concerns to the proper authorities as required by law.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Could there be problems if you or someone else in the family releases information? If you or a member of your family receives private information about you and does not maintain the privacy of that information, there is no way to predict who will have access to that private information. There is no way to predict the risks or damage which could result from unwanted release of that information.

How do you stop your participation in the research? If you prefer to stop participation in this research, you may ask Dr. Garg to destroy any record of your participation in this research and to destroy any sample with your name on it. You will not be asked for further information or samples. Your identity will be removed from all research records. However, the resulting data from the research will not be discarded. Copies of DNA and/or growing cells made from your samples will not be destroyed.

Samples sent to other scientists cannot be identified and destroyed because your name was removed before the samples were shipped to other medical centers.

