INFORMED CONSENT FORM

Official title: Phase 2 Study of Obeticholic Acid for Lipodystrophy patients.

NCT number: NCT02430077

IRB Approved date:04-16-2018

The University of Texas Southwestern Medical Center at Dallas
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital of Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:
Phase 2 Study of Obeticholic Acid for Lipodystrophy patients**.**

Funding Agency/ Sponsor: **National Institutes of Health**

Study Doctors:
Abhimanyu Garg, M.D.
Zahid Ahmad, M.D.
Jeffrey Browning, M.D.

Research Personnel:
Claudia Quittner, RN, BSN, MS
Chandna Vasandani, Ph.D.

You may call these study doctors or research personnel during regular office hours at 214-648-9296. At other times, you may call them through the operator by calling 214-645-5555 and pressing 0. You will need to ask the operator to have the study doctor paged. Please ask the operator to page Dr. Abhimanyu Garg, or Dr. Zahid Ahmad.

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.

Why is this study being done?
This study is being done to evaluate the efficacy (ability to produce desired effect of the intervention) and safety of Obeticholic acid (OCA) therapy in treating hepatic steatosis (fatty Liver) in patients with familial partial lipodystrophy (FPL), Dunnigan variety. Familial partial lipodystrophy (FPL) is a rare genetic disorder characterized by selective, progressive loss of body fat (adipose tissue) from various areas of the body.

Because this is a research study, Obeticholic acid will be given to you only during this study and not after the study is over.

Why is this considered research?

This is a research study because Obeticholic acid, a modified bile acid (bile acids are produced by the liver to help with digestion of fats) is an investigational drug and has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of hepatic steatosis (fatty liver) in patients with lipodystrophy. Lipodystrophy is a body fat disorder and is characterized by selective loss of fat tissue.

The following definitions may help you understand this study:

- Double-blind means neither you nor the researchers will know when you are receiving study drug, Obeticholic acid or placebo.
- Placebo-controlled means that in one of the study periods you will get a placebo. A placebo looks like the investigational drug but it includes no active ingredients.
- Randomization means you will be placed by chance (like a flip of a coin) to receive either Obeticholic acid or placebo in the first study period.
- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to participate in this research because you have a body fat disorder known as familial partial lipodystrophy, a condition which results in areas of selective or generalized fat loss, and in addition, you have hepatic steatosis, or a fatty liver (excess fat accumulation in the liver). Having fatty liver can place you at risk for other serious liver problems such as hepatitis (inflammation of the liver) or cirrhosis (scarring and abnormal function of the liver). Currently, there are no standard treatments that are proven to be safe and effective for treating fatty liver, a disease condition.

Do I have to take part in this research study?"
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?
About 20 people will take part in this study at UT Southwestern.

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

If you are found to be eligible, during the baseline period, you will continue your usual diet and other lifestyle measures without changing any medications for 1 month in order to establish a baseline state. Three blood samples will be obtained during this period at the Clinical and Translational Research Center. Following the baseline period, you will be randomized to receive

either Obeticholic acid (OCA) or an identical placebo in the dose of 25 mg/day for a period of 4 months and then will receive the other treatment (OCA or placebo) for 4 months. There will be a wash-out period of 4 months in-between the two study periods. You will be in this study for approximately 12 months.

Screening Procedures

To help decide if you qualify to be in this study, the researchers may ask you questions about your health, including medications you take and any surgical procedures you have had.
You will be asked about any previous testing done regarding liver diseases or function, such as a liver biopsy or tests for hepatitis.
You will have the following evaluations: a physical exam including weight, blood tests for liver function and liver diseases, a general chemistry panel with triglycerides and cholesterol (blood fats), insulin, a complete blood count, urine tests, and a urine pregnancy test if appropriate.
You will fill out a questionnaire about your quality of life, your diet and also your gastrointestinal symptoms. You will have an MRS (magnetic resonance spectroscopy) scan of your liver, an MRS is an imaging scan which does not involve radiation and which shows if you have a fatty liver.

Randomization
If the study doctor believes that you qualify to participate in this research, you will take tablets by mouth. The study is a randomized, placebo controlled, crossover design. "Randomized" means that you will be assigned to one of two groups. The study assignment is made in advance by a process similar to flipping a coin. Depending on which group you are assigned to, you will take either active Obeticholic acid tablets or placebo (an inactive substance) tablets for 4 months and then either Obeticholic acid tablets or placebo for another 4 months. There will be a wash-out period of 4 months in-between the two study periods. Whichever treatment group you begin on, after 4 months of that treatment, there will be a wash-out period of 4 months in-between and you will "crossover" to the other treatment group. That is why it is called a "crossover" design.

Neither you, or your study doctor, or other research personnel will know what your study assignment is.

Treatment
Obeticholic acid (25 mg) or placebo will be given in a tablet form.

Procedures and Evaluations during the Research

You will be admitted to the Clinical and Translational Research Center for the baseline evaluations (at the beginning of the two study periods), and at the end of four months during each study period. Biochemical testing and routine urinalysis will be done every 6 weeks during the periods when you are on study drug or placebo. We will provide kits to you for mailing the blood and urine samples using courier service.
During your 3 day stay in CTRC you will have the following tests and procedures or assessments in this study:

Demographic Characteristics, Health History, and Physical Examination: You will be asked to complete questionnaires on demographic characteristics and health history during baseline

period and during the last week of each study period. Height and body mass will be measured by standard procedures.

Serum chemistry, lipoproteins, insulin, and FGF19: Blood will be obtained after overnight (12 h) fast daily. Blood sample will be used for chemistry profile ,(, lipids (blood fats), hemoglobin A1c (a measure of what your average blood glucose levels have been over the past three months) and hormones (e.g. Insulin, and fibroblast growth factor-19)., The test involves drawing about 15 mL (1 tablespoon) on adults of blood in the morning before you eat.

Proton Magnetic Resonance Spectroscopy (MRS): Proton MRS Studies will be performed on you to measure liver fat content. These studies will be performed at 0, 2, and 4 months during each study period. This technique is closely related to magnetic resonance imaging and can accurately measure tissue concentrations of glucose fat. The test involves lying down on a table that slides into the magnet tube.

Magnetic Resonance Imaging (MRI): Your liver size will be measured using MRI. Magnetic resonance imaging is a type of scan that uses magnetic fields and radio waves to make a picture of the liver.

Three-Day Food Record: Dietary intake will be assessed by 3-day food record (two weekdays and one weekend day), a valid and reliable method. The measure will be taken at baseline and each of the follow-up visits. You will be instructed on how to record in detail all the food and drink consumed in the 3-day food record booklet provided. You will also be provided a two-dimensional visual chart of food portions to aid in estimating portion sizes.

Oral Glucose Tolerance Test (OGTT): A 3 hour OGTT will be performed after 10-12 h overnight fast. An intravenous line will be placed for blood drawing. On the day of fasting, you will have a fasting blood sample collected and then you will be Instructed to drink the glucose solution (75 g of glucose in 200 mL of water) over a maximum of 15 minutes (ideally within 5 minutes). Time will be noted. Blood tests will be done at half-hour intervals for three hours to check your glucose and insulin response. A total of 45 mL blood or 3 tablespoons (for adults) will be withdrawn during this test.
The quantity of blood drawn at any one time for adults will be a maximum of 2 1/2 tablespoons. The blood and urine testing, questionnaires and liver MRS scans are evaluation methods for the research team to follow you for the safety, tolerability and effectiveness of the Obeticholic acid therapy for your fatty liver.

How long can I expect to be in this study?

You will be expected to be in the study for a period of 12 months.

What are the risks associated with the study?

Study Procedure/Intervention
Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

Obeticholic acid

Obeticholic acid is an investigational drug.
Obeticholic acid at the proposed dose of 25 mg per day appears generally safe and well tolerated.

The most common non-serious adverse event with OCA therapy in primary biliary cirrhosis (a liver disease affecting bile ducts; PBC) patients and across other trials is pruritus (Itching of the skin). In a multiple dose escalation trial in healthy volunteers OCA was safe and well tolerated at doses up to 100 mg/day without pruritus (Itching of the skin).

Approximately 1023 subjects have been exposed to Obeticholic acid in various trials.

Serious adverse events either possibly or probably related to Obeticholic Acid are rare and include: stroke, ataxia (poor coordination), vertigo (dizziness), chest pain, gastrointestinal bleed, liver toxicity and myocardial infarction (heart attack). A single subject who was taking Obeticholic acid died of myocardial infarction. Although the investigator considered this death to be possibly related to the drug, however, she also had high blood pressure, high cholesterol, obesity and was taking hormone replacement therapy, all of which could have contributed to myocardial infarction. In rare PBC patients flare up of the disease was also noticed.

Additional adverse events associated with OCA include:
Common events: itching, constipation, mouth/throat pain.
Other uncommon events:

- diarrhea, , abdominal pain, stomach discomfort, nausea, vomiting, abdominal distension, jaundice (yellow tone to skin)
- excoriation (skin-picking)
- arthralgia (joint pain),
- peripheral edema (fluid accumulation),
- sinusitis (swelling of the sinus lining)
- pain in extremity, back pain
- myalgia (muscle soreness)
- hemorrhoids
- muscle spasms
- cough
- gastroesophageal reflux disease (heart burn or indigestion)
- fatigue, headache
- upper respiratory infection
- insomnia (sleep disturbance)
- pallor (paleness of skin)
- chest pain
- decreased hemoglobin (decreased blood count)
- anxiety
- headache, dizziness, , depressed mood
- dysmenorrhea (painful periods)
- rash
- nasopharyngitis (viral infection of the upper respiratory system)
- dry eye

- vomiting
- pyrexia (fever)
- epistaxis (nose bleed)
- maculopapular rash (rash characterized by a flat, red area on the skin that is covered with small raised bumps
- Palpitations and urinary tract infection.

Elevations in the liver enzymes (ALT, AST), increased bilirubin and hepatic (liver) adverse events were reported only at the OCA dose of 25 mg mg and above and were reversible with stopping the drug..
Lipid profile changes; including decrease in total and high density lipoprotein (HDL or good) cholesterol have been noted but reversed once OCA drug dosing was stopped.

3-day food recalls: no risk, the inconvenience of the brief time spent.

Quality of life and gastrointestinal symptoms questionnaires: no risk, the inconvenience of the brief time spent.

MRS Risks
There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud banging made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time. If you have any metal clips or plates in your body, you should tell the investigator. You may also experience some discomfort and fatigue from lying still during imaging.

MRI risks
There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud banging made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time.

You may also experience some discomfort and fatigue from lying still during imaging.

If you have any metal clips or plates in your body, you should tell the investigator.
MRI may not be appropriate if you are pregnant or are trying to become pregnant. MRI may not be appropriate if you have permanent eyeliner or eyebrows or any pieces of metal in your body, such as the following:

• heart pacemaker, heart valve replacement, or aortic clips
• metal fragments in your eyes, skin, or elsewhere in your body
• brain clips or pieces of metal used in aneurysm surgery or intercranial bypass
• venous umbrella
• pieces of metal in the body resulting from work as a sheet-metal worker or welder
• clips placed in an internal organ
• prosthetic devices, such as middle ear, eye, joint, or penile implants
• joint replacement.
• hearing aid that cannot be removed

• neurostimulator
• insulin pump
• intrauterine device (IUD)
• shunts or stents
• metal mesh or coil implants
• metal plate, pin, screws, or wires, or any other metal implants

If you have a history of an implanted device or clips in your pelvis (involving your uterus or fallopian tubes) or under your skin, acting as a contraceptive to prevent pregnancy, the MRI technologist will obtain specific information about the make and model of your implanted device to determine if it is safe for you to receive the MRI examination.

OGTT risks: Phlebotomy and line placement for OGTT carries the rare to occasional minimal risk of discomfort, hematoma, infection, fainting and/or vasovagal response. Oral glucose tolerance test carries minimal, occasional risk for nausea and/or vomiting.

Placebo Risk:

During one of the study periods, you will receive a placebo. Taking a placebo may be similar to not taking any medication. During this period your disease/condition may spontaneously get better or worse, just as it may have done without additional treatment.

Blood draws: A blood draw may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.

Fasting: Fasting could cause dizziness, headache, stomach discomfort, or fainting Subjects will also undergo repeated routine fasting phlebotomy for which there is a minimal risk of psychological or physical discomfort.

Urine Sampling: This may cause some inconvenience but there are no risks involved

Other Risks

Since the study drug is investigational when taken alone or in combination with other medications, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study drug. The phone numbers for the study team are on the first page of this document.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks to Sperm, Embryo, Fetus or Breast-fed Infant

The effects of Obeticholic acid on sperm, a pregnancy, or a nursing child are not known. If you are currently pregnant, planning to become pregnant or father a child, or breastfeeding a child, you should not join this study.

Males: being in this research may damage your sperm, which could cause harm to a child that you may father while on this study. If you take part in this study and are sexually active, you must agree to use a medically-acceptable form of birth control. Medically-acceptable forms of birth control include:

(1) surgical sterilization (vasectomy), or
(2) a condom used with a spermicide (a substance that kills sperm).

Females: If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes:
(1) surgical sterilization (such as hysterectomy or “tubes tied”),
(2) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
(3) an intrauterine device (IUD).
If you do become pregnant during this study, you must tell the researchers immediately.

How will risks be minimized or prevented?
Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, monitoring, withdrawal of the subject upon evidence of difficulty or adverse event; referral for treatment, counseling or other necessary follow-up.

Biochemical testing and routine urinalysis will be done every 6 weeks during the periods when you are on study drug or placebo. Telephone contact will be initiated with you every 2 weeks to assess for symptoms such as new or worsening pruritus (itching), abdominal pain, new or worsening fatigue, anorexia, nausea, rash, vomiting, diarrhea, jaundice (yellow skin or sclera, high amber colored urine and pale stools) and vague neuropsychiatric symptoms.
If you live outside of Dallas, blood tests will be arranged every 6 weeks and if there are any abnormalities, you will be asked to either visit us in person (for those living in the Dallas area) or see your primary care physician for physical examination (for those from outside Dallas). We will communicate with your physicians about the lab data and physical examination findings.

Drug will be discontinued immediately if you develop liver decompensation events (e.g., variceal bleed, hepatic encephalopathy, ascites, etc.) and we will not restart the drug even if the events are resolved.

You will be asked to report following symptoms as it will trigger immediate evaluation of for liver

toxicity: new or worsening pruritus (itching), abdominal pain, new or worsening fatigue, anorexia, nausea, rash, vomiting or diarrhea. Even vague neuropsychiatric symptoms have been associated with acute liver failure. If prompt evaluation is not possible, the investigational drug will be immediately discontinued.

You will be asked to withhold drug during intercurrent illness, such as gastroenteritis resulting in dehydration, or other reasons for dehydration, and you will be reevaluated with both biochemical testing and physical exam prior to restarting the drug.

Physical exam and liver biochemistries will be performed at each clinic visit and at any unscheduled visit triggered by your reporting symptoms. If elevations in blood tests trigger reevaluation, then platelet count, INR, albumin, direct bilirubin, electrolytes and creatinine will be included in repeat testing.

What will my responsibilities be during the study?
While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Take the study drug as instructed.
- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Agree to use a highly effective contraceptive method throughout the study and your doctor can discuss the method(s) of birth control or contraception that is appropriate for you.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter, such as vitamins, minerals and purified food substances as well as any herbal remedies as these may affect the study drugs.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or an illness while you are on study even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?
It is possible that your condition or health may or may not improve because of your taking part in this study. However, there is no guarantee that you will benefit in any way. Information learned from this study may benefit others with fatty liver in the future.

What options are available other than being in this study?
You do not have to be in this study to receive treatment for your fatty liver. Instead of taking part in this study, you may choose to receive treatment with other drugs that have been approved for use in this country. There are no established therapies for fatty liver in patients with FPLD. You may try losing weight by controlling your diet and increasing physical activity.

Will I be paid if I take part in this research study?
No. You will not be paid to take part in this research study. There are no funds available to pay for transportation expenses, or lost time away from work and other activities, lost wages, or child care expenses.

For non-local subjects a ClinCard will be given to cover travel incidentals.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. In order to receive study payments, your name, address, date of birth and Social Security Number (SSN) will be collected from you by the research staff. All information will be stored in a secure fashion and will be deleted from the UT Southwestern Greenphire ClinCard system once the study has been completed.

Important Information about Study Payments

1. Your SSN is needed in order to process your payments. Should you decide not to provide your SSN, your study participation payment will be decreased at the current IRS tax rate. Study payments are considered taxable income and are reportable to the IRS.
2. An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.
3. Your payment nformation will not be shared with any third parties and will be kept completely confidential

This payment information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a “hold” on all State payments to you. Such a “hold” could result from your failure to make child

support payments or pay student loans, etc. If this happens, UT Southwestern will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the "hold."

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., study drug, the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care. Please note that the cost of any lipid lowering medicines will be your responsibility.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.
If you experience a research injury, Dr. Garg will provide or arrange for medical treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas.

You retain your legal rights during your participation in this research

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.
Your doctor is a research investigator in this study. He is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

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, any data already generated from your samples will be kept to preserve the value of the study.

If I agree to take part in this research study, can I be removed from the study without my consent?

Yes. The researchers or the study sponsor may decide to take you off this study if:

- Your medical problem becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor, IRB, or IEC, or regulatory agency cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.
- You become pregnant, intend to become pregnant or are nursing a child during this study.

Will my information be kept confidential?

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- NIH
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA) in the U.S. or other countries, involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.
- Researchers who are conducting this study at other research sites

The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study.
The goal of any such research would be to learn more about drugs or diseases or to help design better studies in the future. Your name will never appear in any sponsor reports or publications, or in any future disclosures by the sponsor.

The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled Authorization for Use and Disclosure of Health Information for Research Purposes. You will be asked to sign that form to show that you

give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not, you will not be able to participate in the study

Where can I find additional information about this research study or the research results?

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. It may be many years; however, before research results are posted.

Are there procedures I should follow after stopping participation in this research?
Yes. If you, the researchers, or the sponsor stops your participation in the research, you may be asked to do the following:

- Let the researchers know immediately that you wish to withdraw from the research.
- Return to the research center for tests that may be needed for your safety.
- Return any unused study materials, including empty containers.
- Discuss your future medical care, if any, with the researchers and/or your personal doctor.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Garg or Dr. Ahmad at 214-648-2377 during regular business hours. After hours, on weekends or holidays, please call 214-645-5555 press 0 and ask the operator to page Dr. Garg or Dr. Ahmad for you.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN 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 and have been told who to call if you have any more 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 Date Time AM/PM

_____

Name of person obtaining consent (printed)

_____ _____

Signature of person obtaining consent Date TIME AM/PM