Phase II study of enzalutamide (MDV3100) and gonadotropin-releasing hormone (GnRH) agonist before, during, and after radiation therapy in treatment of patients with high-risk localized prostate cancer

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

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	Phase II study of enzalutamide (MDV3100) and gonadotropin-releasing hormone (GnRH) agonist before, during and after radiation therapy in treatment of patients with high-risk localized prostate cancer
Funding Agency/Sponsor:	Sponsor- UTSouthwestern Medical Center Funding agency- Astellas Scientific and Medical Affairs, Inc.
Study Doctors:	Kevin Courtney, MD, PhD, Yull Arriaga, MD, Raquibul Hannan, MD, PhD, Michael Folkert, MD, Aaron Laine, MD, Neil Desai, MD

You may call these study doctors or research personnel during regular office hours at 214-645-8787. At other times, you may call them at 214-645-4673.

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?
The study is being done to find out whether combining the two FDA approved drugs enzalutamide (an androgen receptor blocker) and gonadotropin-releasing hormone agonist (GnRH agonist) along with radiation therapy for the treatment of prostate cancer is safe and well-tolerated. The combination of enzalutamide plus a GnRH agonist is a standard of care treatment option for patients with metastatic prostate cancer that no longer responds to treatment with a GnRH agonist alone. The combination of a GnRH agonist plus radiation therapy (with or without an older androgen receptor blocker drug) is a standard of care treatment option for patients with high-risk localized and locally advanced prostate cancer. The combination of all three (enzalutamide, GnRH agonist, and radiation therapy) has not been previously tested in patients with localized prostate

cancer. It is possible that combining all three may provide more effective treatment for patients with high-risk localized or locally advanced prostate cancer. At UTSW, we have decided to use Lupron® as the GnRH medication for the study purposes.

Why is this considered research?
This is a research study because these two drugs and radiation therapy have not been combined. The researchers are interested in learning if this combination is safe and well-tolerated and possibly more effective in treating your condition/disorder.

The following definitions may help you understand this study:

- 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 take part in this study because you have been diagnosed with high-risk localized or locally-advanced prostate cancer, OR you have physical examination findings (an abnormal prostate on a digital rectal examination) and findings from blood work (elevation in your PSA) that are concerning for the possibility that you may have high-risk localized or locally-advanced prostate cancer and warrant further evaluation by prostate biopsy.

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 15 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.

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you

questions about your health, including medications you take and any surgical procedures you have had. The screening procedures could take from 30- 120 minutes to complete. The scans could be done on other days taking up to 2 hours to complete.

You may also have to fill out certain forms or have the following exams, tests or procedures:

Medical History
Demographic information
Review both eligibility criteria and other medications that you take
Physical exam including vital signs, height and weight
Questionnaire completion
Blood tests – approximately 2 tablespoons of blood will be collected
CT of the abdomen and pelvis
Bone scan
Chest x-ray or CT of the chest
Pelvic MRI
Prostate biopsies performed as standard of care and additional samples for research purposes

Study Medication/Intervention

You will receive treatment with enzalutamide by mouth plus Lupron (the GnRH agonist) intramuscular (into your muscle) for 8-10 weeks prior to starting your radiation therapy.

During radiation therapy you will continue to receive the two medications for the duration of the radiation therapy. This will be approximately 8-10 weeks. Each radiation visit could last from 30-120 minutes.

After you have completed your radiation therapy you will continue to receive the two medications until you have reached a total of 24 weeks duration of the two medications.

After you have completed the 24 weeks of the two drug combination you will continue to receive GnRH agonist therapy until you have reached 24-36 months of total GnRH agonist treatment. The decision to continue GnRH agonist treatment for a total of 24 vs 36 months will be at the discretion of your treating physician.

Procedures and Evaluations during the Research

One to two weeks prior to starting your treatment you will have a pelvic MRI and transrectal ultrasound (TRUS)-guided prostate biopsies. If you have not undergone previous prostate biopsies from which you have been diagnosed with high-risk prostate cancer, then both the standard diagnostic biopsies and research biopsies

will be performed at the same time. If you have previously undergone prostate biopsies and been diagnosed with high-risk prostate cancer, you will undergo an additional TRUS-guided biopsy procedure to obtain prostate tissue for research purposes. This could take up to 2 hours to complete.

Weeks 1-24 – prior to each cycle of enzalutamide and GnRH you will have the following tests done:

Physical exam including vital signs
Blood work – approximately 2 tablespoons of blood will be taken from a vein in your arm

This visit could take from 30 to 60 minutes.

Week 8 – You will have magnetic resonance imaging (MRI) of your pelvis. For this procedure, you will lie quietly inside a large, doughnut-shaped magnet for about sixty minutes. You will also have fiducial marker (gold seed) placement and TRUS-guided targeted prostate biopsies. *This visit could take up to 120minutes to complete.*

Every 4 weeks after you have started taking enzalutamide you will have a physical exam with vital signs and blood drawn. You will have approximately 2 tablespoons of blood drawn at each of these visits. These visits can last from 30- 60 minutes.

This table outlines your study visits:

	Pre-study Days -56 to - 14	Day 1	Every 4 weeks (weeks 4-48)	Week 8	End of study visit
Informed Consent	X				
History and PE	X	X	X		X
Performance Status	X	X	X		X
Blood tests	X	X*	X		X
CT abd/pelvis					
Chest X-ray or CT chest	X				
Bone scan	X				
MRI pelvis	X			X	
TRUS-guided prostate biopsy	X			X	

*Blood tests will be repeated on day 1 if pre-screening blood work was done greater than 28 days prior to day 1.

The extra prostate biopsies and extra blood sample at the screening visit and two months on treatment in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your research prostate biopsies and extra blood sample to find or treat a

medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the prostate biopsies and extra blood test done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor. The biopsies can take up to 120 minutes.

Procedures for storing of extra or left over samples
Some of your blood and prostate samples may be stored for future research. These samples will have all identifying information removed including your name, date of birth, medical record number. They will be labeled with a code that only the study staff will have access to. These samples may be used for future research studies on prostate cancer or other diseases.

How long can I expect to be in this study?
You participation in this study may last up to 36 months.

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. You may be asked if you are willing to complete some study termination tests.

What are the risks of 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.

Enzalutamide (MDV3100) may cause some, all or none of the side-effects listed below.

You may experience side effects while on the study drug. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you drugs to help lessen side effects. Side effects may go away soon after you stop taking study drug. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you may have while taking part in the study.

In the Phase 3 study CRPC2, 800 patients were treated with enzalutamide (MDV3100)at a dose of 160 mg daily and 399 patients were treated with placebo (a substance that does not contain any active drug). Side effects reported in at least 5% of enzalutamide (MDV3100)-treated patients and at a rate that was at least 2% higher than in placebo-treated patients included fatigue, diarrhea, hot flush, pain in muscles and bones, headache, trouble sleeping, anxiety, high blood pressure, and cold symptoms (congested nose and sore throat). Other side effects reported in less than 5% of enzalutamide (MDV3100)-treated patients and at a higher rate than placebo-treated

patients included falls, dry skin, itchiness, thinking or memory problems, and hallucinations (seeing or feeling things that are not there). Seizures (such as convulsions) have been infrequently reported in patients (less than 1% of patients) receiving enzalutamide (MDV3100) and not in placebo-treated patients. Due to this potential risk of seizure, please inform your study doctor if you have ever had a condition that may increase the risk of seizures, such as prior history of seizure, brain injury, or brain tumor; stroke; or history of alcoholism.

There are some medicines that are known to increase the chance of having a seizure. These medicines include but are not limited to:

- Aminophylline/theophylline
- Atypical antipsychotics (e.g., clozapine, olanzapine, risperidone, ziprasidone)
- Bupropion
- Lithium
- Meperidine (Demerol)
- Phenothiazine antipsychotics (e.g., chlorpromazine, mesoridazine, , prochlorperazine, thioridazine)
- Tricyclic and tetracyclic antidepressants (e.g., amitriptyline, desipramine, doxepin, imipramine, maprotiline, mirtazapine)

These medicines may increase your risk of developing seizures when used with enzalutimide (MDV3100). It is important for you to tell your study doctor all of the medicines you are taking.

There have been rare reports of posterior reversible encephalopathy syndrome (PRES), a rare, reversible condition involving the brain, in patients treated with enzalutamide. If you have a seizure, worsening headache, confusion, blindness or other vision problems, please contact your doctor right away. Your doctor will stop enzalutamide if you develop PRES.

In addition, some medicines may affect how enzalutamide (MDV3100) is broken down by your body. Caution should be used when taking certain medicines or substances because they may increase the amount of enzalutamide (MDV3100) in your blood. These include but are not limited to clarithromycin, gemfibrozil, grapefruit, itraconazole, and ketoconazole. Also, caution should be used when taking certain medicines or substances because they may lower the amount of enzalutamide (MDV3100) in your blood. These include but are not limited to carbamazepine, phenytoin, rifampin, and St. John’s wort.

Because enzalutamide (MDV3100) blocks the action of the male sex hormone, it is expected to cause infertility and impotence and may contribute to loss of muscle and bone, hot flashes or breast growth. Because you can only be in this study if you are taking other drugs that decrease male sex hormones or have had a bilateral orchiectomy, you may or may not notice additional changes related to decreased male

sex hormone action after receiving enzalutamide (MDV3100). Even though the risk of getting your partner pregnant while taking enzalutamide (MDV3100) is low, to participate in this study you must agree to utilize effective birth control methods to ensure that your partner does not become pregnant.

Most men participating in this study may experience long term impotence due to the overall treatment for their prostate cancer.

Possible risk and side effects related to the *GnRH*:
Most Common (30% or more)
• Hot flashes
• Erectile Dysfunction
• Feeling tired
• Nausea
Very Common (10% or more to less than 30%)
• Constipation
• Headache
• Loss of appetite
• Diarrhea
• Dizziness
• Skin rash, covering part or most of body
• Joint pain
• Increase in a type of fat in blood
• Difficulty breathing during physical activity
• Changes in electrocardiogram (QTc, length)
• Hot flush
• Bone or liver enzyme increased in blood
• High blood sugar (glucose)
• Dizziness
• Protein in urine
• Change in sense of taste
• High blood pressure
• Low white blood cells

Patients receiving treatment with LHRH agonists should undergo periodic monitoring of blood glucose and/or glycosylated hemoglobin (HbA1c) for signs of developing diabetes or worsening of blood glucose control in patients with diabetes, and also for the signs and symptoms suggestive of the development of cardiovascular disease.

<u>MRI</u>
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 intracranial 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

You may receive a contrast agent that is FDA-approved and used routinely for MRI exams. It contains a material called Gadolinium (dye solution used to highlight organs or tissues during imaging). The injection of Gadolinium may cause discomfort like headache, nausea, strange taste, or coldness at site of injection. These symptoms occur in less than 1 out of 20 patients receiving Gadolinium and go away quickly. There is a small risk of a severe allergic reaction that can cause breathing difficulties and/or low blood pressure, and these symptoms are extremely rare (approximately 1 in 10,000 to 1 in 100,000 administrations). In the unlikely event you experience these symptoms, a physician and nursing staff will be available to evaluate and, if necessary, provide treatment.

People with severe kidney failure who receive Gadolinium (dye solution used to highlight organs or tissues during imaging) are at risk of developing a disorder called Nephrogenic Systemic Fibrosis (NSF). This disease can cause wide spread tissue scarring or hardening (fibrosis). In rare cases NSF can lead to lung and heart problems and cause death. If you have severe kidney failure and receive gadolinium, the risk of developing NSF is 1-5%. We may perform a blood test 30 days before your MRI to check how well your kidneys are working before you receive the Gadolinium. This test may be repeated closer to your MRI appointment if your medical condition has changed. If your kidneys

are working at levels known to be at risk for NSF, you will not receive Gadolinium. You will not receive Gadolinium for research purposes if you have sickle cell disease (a disease of the blood cells) since it may put you at risk of developing hemolysis (breakdown of blood cells).

Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

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
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).

_____I agree to use medically acceptable birth control for 90 days after stopping Enzalutamide

_____ I do not agree to use medically acceptable birth control for 90 days after stopping Enzalutamide

Risks of Radiation – Diagnostic Test
The radiation dose that you will get from diagnostic tests is medically indicated for your condition and it is the same that you would get if you were not involved in this research study.

Risks of Radiation – Radiation Therapy
The radiation therapy used in this research is the standard radiation therapy for your health problem; therefore, the risk of harm to your body is the same. Your radiation doctor will discuss the known risks of radiation therapy with you and ask you to sign a separate specific treatment site consent form.

High-dose radiation treatments to or near a man's testicles may produce harmful changes that could be passed on to children through a sperm.

You must avoid fathering a child until ten weeks after the end of all radiation therapy.

After that period, there is much less risk of harmful changes to sperm. Even then there is still an unknown amount of risk.

Possible side effects of radiation therapy to the prostate include:
Short Term effects: Inflammation of the bowel causing cramping and diarrhea; inflammation of the rectum and anus causing pain, spasm, discharge, bleeding; bladder inflammation causing burning, frequency, spasm, pain, and/or bleeding; skin changes: redness, irritation, scaliness, blistering or ulceration, coloration, thickening, hair loss; depression of blood counts leading to increased risk of infection and/or bleeding.

Long Term effects: bowel damage causing narrowing or adhesions of the bowel with obstruction, ulceration, bleeding, chronic diarrhea, or poor absorption of food elements and may require surgical correction or colostomy; bladder damage with loss of capacity, frequency of urination, blood in urine, recurrent urinary tract infections, pain, or spasm which may require urinary diversion and/or removal of the bladder; changes in skin texture and/or coloration, permanent hair loss, and scarring of skin; bone damager leading to fractures; testicular damage causing reduced sperm counts, infertility, sterility, or risk of birth defects; impotence (loss of erection) or sexual dysfunction; swelling of the genitalia or legs; nerve damage causing pain, loss of strength or feeling in legs, and/or loss of control of bladder or rectum; fistula between the bowel and other organs.

Prostate Ultrasound and Biopsy: The transrectal ultrasound may be associated with discomfort and very rarely, rectal bleeding. A transrectal ultrasound involves inserting a probe into the rectum. The machine visualizes (allows the doctor to see) the rectum and prostate by sending high frequency sound waves (signals) from the probe and measuring the waves as they are reflected back, producing images on a screen.

During the prostate biopsy procedure, up to twelve very small samples of tissue are withdrawn from the prostate through a needle. You may feel a stinging sensation each time a sample is taken, but usually any soreness or discomfort quickly passes. After the biopsy, you may experience minor bleeding in the urine or rectum, or blood-tinged ejaculate (the fluid released by the prostate during sexual intercourse). There are also small risks of temporary inability to urinate or infection. An antibiotic is prescribed by your doctor to prevent infection.

Risks of Blood Drawing
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely.

You will have 30 tablespoons of blood collected because you are in this research study.

Other Risks
There may possibly be other side effects that are unknown at this time. If you are

concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?
You will be monitored periodically during the study through study visits to make sure that you are doing well. If you have any problems, you can contact the study staff at the numbers on the front of this form.

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:

- 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 (tablets) in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- 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.
- Tell your regular doctor about your participation in this study.
- Carry information about the research medication in your purse or wallet.
- Report to the researchers any injury or illnesses 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?
If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this

research.

We hope the information learned from this study will benefit others with high-risk localized or locally advanced prostate cancer in the future. Information gained from this research could lead to better treatment.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have other options. Standard of care treatment may include, depending on evidence of pelvic nodal involvement and your overall clinical status, androgen deprivation therapy combined with radiation therapy OR in some cases a radical prostatectomy. Taking part in another study may also be an option. You may also elect not to receive any treatment after discussing with your personal physician about these options.

Please talk to the researchers or your personal doctor about these options.

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 to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

The study will pay for your parking at UT Southwestern during study related visits. The study staff will stamp your parking ticket that you are given by the valet so that you will not have to pay for the study visits. Please present your parking ticket to the study staff when you come in for your appointment.

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., the extra blood draw, research biopsies) . The enzalutamide being used in this study is being provided by the study sponsor so you will not have to pay for this medication.

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.

The GnRH agonist in this study is considered to be standard of care so you or your insurance company will be responsible for the costs of this medication.

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.

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

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.

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.

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 I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or 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 cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

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:

- Astellas Pharma
- Representatives of government agencies, like the U.S. Food and Drug

Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.

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.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

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.

Is there anything else I should know before I decide?
Drs. Margulis and Raj have financial interests in the company sponsoring this study. You should feel free to ask questions about this.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Courtney at 214-645-8787 during regular business hours and at 214-645-4673 after hours and on weekends and holidays.

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.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time

Interpreter Statement:

I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature on the associated short form.

_____

Name of Interpreter (Printed)

_____ _____ _____ AM / PM

Signature of Interpreter Date Time