Official title: Investigation to Minimize Prolapse Recurrence Of the Vagina using Estrogen (IMPROVE)

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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:	Investigation to Minimize Prolapse Recurrence Of the Vagina using Estrogen (IMPROVE)
Funding Agency/Sponsor:	National Institutes of Health (National Institute on Aging)
Study Doctors:	David D. Rahn, MD (primary) Joseph I. Schaffer, MD; Marlene M. Corton, MD; Clifford Y. Wai, MD; Sunil Balgobin, MD; R. Ann Word, MD
Research Personnel:	Agnes Burris, RN; Juanita Bonilla

You may call these study doctors or research personnel during regular office hours at 214-590-6547. At other times, you may call them at 214-648-6430.

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?

Pelvic organ *prolapse* refers to the bladder, uterus, and/or rectal tissue bulging down into the vagina causing a feeling of fullness or pressure. This study is being done to see if vaginal estrogen cream (Premarin®) improves the strength of the vaginal walls and its supporting connective tissue to help prevent recurrence of pelvic organ prolapse after surgical repair. Although the U.S. Food and Drug Administration [FDA] approves this drug for other uses, it is not approved specifically for the prevention of pelvic organ prolapse after surgical repair. We also want to see if vaginal estrogen cream has a beneficial effect on other pelvic floor disorders such as overactive bladder, urinary incontinence, and pain with intercourse.

Why is this considered research?
Menopause and aging are known risk factors for pelvic organ prolapse and other pelvic floor disorders. Unfortunately, sometimes vaginal prolapse can reoccur even after a surgery to repair the prolapse. This is a research study because vaginal estrogen cream will be compared to an inactive (placebo) cream to determine if the estrogen cream helps *prevent recurrence* of prolapse and/or helps improve symptoms of other pelvic floor disorders. It is unknown whether the addition of vaginal estrogen will strengthen supportive structures, but to maximize the potential benefit of the estrogen cream, it will be used for several weeks before the surgical repair and for one year following repair while normal, healthy scarring occurs. Premarin® cream has been approved by the FDA to treat thinning of the vaginal wall after menopause, which is often associated with symptoms of dryness, burning, or pain with intercourse, but it has not specifically approved Premarin® cream for prevention of prolapse recurrence after surgical repair.

In addition, a small biopsy from the vaginal wall taken at the time of surgery (optional) will be used to determine how vaginal estrogen cream may change the “building-up” and “breaking-down” of the supportive deeper layer of the vaginal wall. Blood is collected (also optional) to see if vaginal estrogen cream application changes estrogen levels in the blood stream and to determine if your DNA (i.e., your genetic code) may help predict how strong your surgical repair will be.

The following definitions may help you understand this study:

- Placebo-controlled means that some participants will get a placebo. A placebo looks like the investigational vaginal cream but it includes no active ingredients. In this study, the placebo will be a cream that does not contain estrogen.
- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups.
- Double-blind means neither you nor the researchers will know which type of vaginal cream you are receiving.
- 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 are a postmenopausal woman who is not currently using estrogen as a medication and are planning surgery to repair your pelvic organ prolapse.

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 75 people will take part in this study at UT Southwestern or Parkland Health & Hospital System. This study also is taking place at a number of other medical facilities around the country. There will be a total of 222 people participating in this research study throughout the United States.

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. A physical exam that includes determining the severity of your prolapse will be done; this is standard medical care for your condition. If you are 55 years old or younger and have had a hysterectomy but still have one or both ovaries, your health care provider will check the acidity/pH of the vaginal wall using a cotton swab of the vaginal wall. This screening procedure will not be done if you are older than 55 years or if you still have your uterus.

Group Assignment
If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive either estrogen vaginal cream or a vaginal cream that does not contain estrogen. You have a 1 in 2 chance of receiving the estrogen cream and 1 in 2 chance of receiving the placebo vaginal cream.

The group you will be in is decided by a computer randomization program. Neither you nor the researchers will be allowed to choose which group you are assigned to.

Study Medication/Intervention
If you decide to participate in the study, you will apply either:

- 1 gram of vaginal estrogen cream, or
- 1 gram of placebo vaginal cream

The cream should be placed in the vagina every night with the provided applicator or your fingertip for 2 weeks, then twice-weekly until your surgery (i.e., for about 4 to 6 more weeks). As soon as possible after surgery (i.e., as soon as you are discharged), resume the twice-weekly application of the cream for 1 year.

Procedures and Evaluations during the Research

Your participation in the study will include your routine clinic visits (i.e., baseline surgery scheduling, pre-operative visit, and postoperative visits at approximately 1, 6, and 12 months after surgery). As a part of the research study, we also request you return for a clinic visit 24 and 36 months after surgery, and we will call you by phone approximately 3, 9, 18, and 30 months after surgery to see how you are doing. During most of the in-person clinic visits, a physical examination to quantify your degree of prolapse (called the "**POP-Q**") will be performed as a standard of care. However, these questionnaires, procedures, and evaluations listed below will be performed because you are a participant in this research study:

Questionnaires (together, these add about 30-45 minutes more to a routine clinic visit):

1. Pelvic floor distress inventory (**PFDI-20**), Pelvic floor impact questionnaire (**PFIQ-7**), and Pelvic organ prolapse/ urinary incontinence sexual questionnaire (**PISQ-IR**). These 3 questionnaires ask about symptoms relating to prolapse, urinary issues, and colon/rectal problems and how these impact your daily life and your sexual function. These 3 questionnaires are routinely asked of patients first presenting to our Urogynecology clinic with complaints of prolapse.
2. Vaginal atrophy symptom questionnaire (**VASQ**): this asks you about five possible symptoms you may have related to lack of vaginal estrogen
3. Body image questionnaire (**BIQ**): this short questionnaire asks about how pelvic organ prolapse may impact how you feel about your body
4. General quality of life questionnaire (**SF-12**): this asks general questions about both your physical and mental quality-of-life
5. Patient Global Impression of Severity (**PGI-S**) and of Improvement (**PGI-I**): these single-question tools ask about how severe your prolapse symptoms are and whether they have improved following surgery

Specimens:

1. Vaginal maturation index (**VMI**): this is a measurement of how well estrogenized the vagina is. A soft bristled brush (similar to that used in a Pap smear) or plastic spatula is used to gently swab the wall of the upper vagina. This test gives a measure of estrogen's effect on the vaginal skin.
2. Blood: two teaspoons (two tubes) of blood will be drawn from your arm by needle stick. One tube is used for tests to determine estrogen levels in your blood. The second tube of blood will be stored for later DNA analysis to learn

whether your particular genetic code may help predict how strong your surgical repair is.

3. Vaginal wall biopsy: a small (~1 x 1.5 cm) biopsy (about the size of a small marble) will be obtained from the vaginal wall at the time of your surgical repair (i.e., under anesthesia). This will be obtained from tissue routinely removed during repair of your vaginal prolapse. Typically, this tissue is discarded during surgery as leftover tissue that is not needed for diagnosis, but we wish to use this tissue biopsy for research purposes. Do you agree that this "leftover" tissue may be used for research purposes?

_____ Yes _____No

Study Visits:

	Surgery scheduling visit (enroll-ment)	Pre-operative visit	Day of surgery	Post-operative time (months):								
				1	3	6	9	12	18	24	30	36
Questionnaires: PFDI-20, PFIQ-7, PISQ-IR, VASQ, BIQ, SF-12, PGI-I or PGI-S	**X**	**X**		**X**		**X**		**X**		**X**		**X**
POP-Q exam	**X**			**X**		**X**		**X**		**X**		**X**
VMI	**X**		**X**					**X**				
Blood sample	**X**							**X**				
Vaginal biopsy			**X**									
Distribution of study cream & refills	**X**		**X**		**X**	**X**	**X**					
Telephone call					**X**		**X**		**X**		**X**	

The VMI, blood sample, and vaginal wall biopsy 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 blood results 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 VMI, blood sample, and vaginal wall biopsy done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

Procedures for storing of extra or left over samples

- Samples (tissue, blood) will be labeled with a unique research study number. No personal identification information will be on the label.

- Samples will be stored in Dr. R. Ann Word's laboratory at UT Southwestern.
- Access to the samples will be limited to Drs. Rahn and Word and laboratory personnel in Dr. Word's laboratory.

Will my samples be used for genetic testing?

Yes, if you agree, one of the tubes of blood you provide will be used for genetic research. Up to 1 teaspoon of blood will be drawn from a vein in your arm with a small sterile needle for genetic analysis. This is the standard method used to obtain blood for routine hospital tests. We may ask for a second blood sample if the research laboratory cannot process the first sample.

What is DNA?

DNA means *deoxyribonucleic acid*. DNA is the substance in our cells which contains information we inherited from our parents and other family members. Your DNA contains "genes" which predict things like physical characteristics (eye color, hair color, height, etc.) and may also be a factor in whether you develop or are at risk of developing certain illnesses or disorders.

What is genetic testing?

Genetic tests look for naturally occurring differences in a person's genes, or the effects of specific genes. These differences could indicate an increased chance of getting a disease or condition. Genetic testing includes gene tests (DNA testing) and sometimes biochemical tests (protein testing) if it relates to a specific gene.

In gene tests, DNA in cells taken from a person's blood, body fluids or tissues is examined for differences. The differences can be relatively large - a piece of a chromosome, or even an entire chromosome, missing or added. Sometimes the change is very small - as little as one extra, missing or altered chemical within the DNA strand. Genes can be amplified (too many copies), over-expressed (too active), inactivated, or lost altogether. Sometimes pieces of chromosomes become switched, turned over or discovered in an incorrect location.

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.

What will happen to the samples collected for this research?

Drs. Rahn and Word will compare information about the health of participants with the results of research tests using their DNA.

De-identified data, including your medical history and results of tests, can be shared by releasing it into scientific databases, including those maintained by the National Institutes of Health (NIH). Sharing this information will help advance medicine and medical research by allowing other researchers to use this information in future research projects. The data will be stored and shared in a manner that would not allow someone to identify you. Please understand that this information cannot be removed once deposited in these databases.

How long will my samples be kept?

Drs. Rahn and Word will keep your sample in a research laboratory at this medical center until it is all gone, becomes unusable or until they decide to discard the sample.

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

May other researchers use my sample?

When you provide a sample for purposes of this study your sample becomes the property of The University of Texas Southwestern Medical Center and may be used for future studies or provided to other investigators at other medical research facilities without any identifiers.

Who decides which research scientists may receive samples of my DNA?

Drs. Rahn and Word will decide which researchers at this medical center and at other medical centers may receive samples of your DNA. 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 my sample be used for other purposes?

No. Your samples or your DNA will only be used for research.

Research tests using your sample may possibly result in inventions or procedures that have commercial value and are eligible for protection by a patent.

Compensation for any future commercial developments is not available from the University of Texas Southwestern Medical Center at Dallas, its researchers 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 without expectation of acknowledgment, compensation, interest in any commercial value or patent, or interest of any other type. However, you retain your legal rights during your participation in this research.

Will the results of research tests be reported to me?

No. Drs. Rahn and Word will use samples of your DNA only for research. The samples will not be used to plan your health care.

Permission to share samples for genetic testing

You have the option to elect to share your samples for the purpose of genetic research as described above. (A "no" answer will not disqualify you from participating in the main study.)

Yes _____ initials. I do allow the use of my samples for genetic research.

No _____ initials. I do not allow the use of my samples for genetic research.

How long can I expect to be in this study?

Your participation will begin approximately 6-8 weeks before surgery and then continue until the main endpoint one year after surgery, which is when the study cream application period is over. In addition, we would like to see you once a year for two more years after the main endpoint (i.e., for about three years in total). The tissue and blood samples will be kept in a research laboratory at this medical center until it is all gone, becomes unusable, for up to 5 years after the clinical portion of the study ends, or when the investigators decide to discard the sample.

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 and questionnaires.

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.

Premarin® vaginal estrogen cream may cause some, all, or none of the side-effects listed below.

Minor side effects:	Percent of patients:
• Vaginal itching	2 to 3%
• Breast tenderness	2 to 3%
• Vaginal discharge	6 to 11%*
• Joint ache	7 to 9%*
• Headache	10 to 13%*

* = in clinical studies, the rates of these side-effects were about the

same in patients treated with estrogen vaginal cream as in those treated with placebo cream

Serious side effects:

- Stroke, blood clots in the lungs or legs — Less than 1%

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 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 about 3 total teaspoons total of blood collected because you are in this research study.

Placebo

If you receive a placebo, you will not receive active vaginal estrogen cream. Since estrogen cream is not standard for women undergoing surgery for pelvic organ prolapse, this is not a problem. The placebo cream, however, may still cause discomfort, itching, or vaginal discharge. If these side effects become severe, your participation in the research will stop. If this happens, your study doctor can discuss alternative care with you.

Biopsy

There are no additional risks since the biopsy will be obtained after the tissue is removed during the course of surgical pelvic organ prolapse repair.

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?

Participation in this study will be offered only to those women who meet the strict inclusion criteria and do not have any of the listed exclusion criteria. The study's inclusion criteria are restricted to those women who the study provides the greatest potential for benefit and minimal potential risk. Blood draws will be completed by

experienced nurses or trained phlebotomists. The vaginal biopsy will be completed under general anesthesia at the time of your scheduled surgery by experienced surgeons. Questionnaires will be administered and examinations performed in private exam rooms. If at any point during the study period you no longer want to participate either from perceived inconvenience or because you experience side effects from the treatment cream, you will be withdrawn from the study.

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, including reliably continuing to apply the study cream vaginally twice per week (after the initial 2 weeks of nightly application). If you agree to it (initial below), the researchers can help you remember by sending reminder emails or text messages to you to not forget your cream.

  I agree _____ (**do NOT agree** _____) to permit the study doctors or research personnel to send me reminder emails or text messages to use my study cream. I may opt out of these reminder messages at any time.

  Email address: _____ Mobile phone: _____

- Let the researchers know if your telephone number or address changes.
- Store study materials (i.e., the treatment cream and applicators) in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- ***Return all unused portions of study cream tubes*** (including empty tubes) to the research nurse or study investigators.
- 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.
- 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. Based on prior studies of preoperative estrogen cream use, the connective tissue beneath the vaginal wall appears thicker and with more strong collagen, which could be helpful for suture placement at the time of prolapse repair surgery. Continued use of estrogen cream *after* surgery may minimize breakdown or reorganization of this connective tissue and could possibly decrease recurrence rates of prolapse after surgical repair, although this remains unproven. Vaginal estrogen is known to help with symptoms of vaginal dryness and pain with intercourse, but it is unclear if it will help with other pelvic floor disorders such as overactive bladder and urinary incontinence in postmenopausal women.

We hope the information learned from this study will benefit others with pelvic organ prolapse planning surgical repairs in the future. Information gained from this research could lead to better quality of repairs and help to prevent repeat surgeries.

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 pelvic organ prolapse. Participation in this study is in addition to your already-planned surgical repair, and you have the option of continuing with surgery without using the study cream. Instead of being in this study, you also have the following options for managing pelvic organ prolapse:

- No treatment (observation)
- Nonsurgical management of prolapse using a silicone vaginal ring device known as a pessary

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

Will I be paid if I take part in this research study?
Yes. You will be paid $50.00 for participation at each of the baseline, preoperative, and 1-month postoperative study visits. You will be paid $75.00 for participation at the 6-

month postoperative visit. You will be paid an additional $100.00 for participation at the 12-month postoperative study visit. You will be paid an additional $75.00 for participation at the 24-month postoperative study visit and $75.00 at the 36-month postoperative study visit. If you stop taking part in this study or are withdrawn by the research team, you will receive payment for only the visits you have completed. For example, if you complete the baseline and preoperative study visits only, you will be paid $100.00 total.

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.

How will I be paid?

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit card 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 completed.

Important Information about Study Payments

1. Your SSN is needed in order to process your payments. Should you decide not provide your SSN, your study participation payment will be decreased at the current IRS tax rate. Study payments are considered taxable income and re 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 ClinCard payment information will not be shared with any third parties and will be kept completely confidential.

This 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., 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.

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 at Dallas or Parkland Health & Hospital System.

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. S/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:

- The National Institutes of Health/ National Institute on Aging
- 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.

Pfizer, Inc., the producer of Premarin® cream, will be notified of any serious adverse events that may occur during the course of this study using your study identification number, but your actual name and identifying information will not be given.

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 study
- Return any unused materials, including empty tubes
- Discuss your future medical care 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. Rahn 214-648-6430 during regular business hours and at 214-913-0100 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.

_____

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