Prospective Randomized Controlled Trial for Pain Relief after Office Ureteral Stent Removal

Study Protocol and Statistical Analysis Plan

NCT04112160

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1. Introduction and Purpose:
Ureteral stents placed after ureteroscopy (URS) for nephrolithiasis can be extremely bothersome for patients in the post-operative period. Even more troubling, a subset of patients experience debilitating renal colic for hours after the stent is removed despite use of narcotic analgesics. The purpose of this study is to determine if the use of pre-emptive ketorolac will prevent or reduce the acute pain experienced by some patients after stent removal.

2. Background:
Nephrolithiasis is a prevalent disease in the United States increasing to nearly 9% in the last decade.[1] Recently, there has been increasing attention focused on improving health-related quality of life (HRQOL) for patients with nephrolithiasis.[2] While randomized controlled trials (RCTs) are limited in this area, HRQOL is diminished in patients undergoing surgical intervention for nephrolithiasis, especially for those in whom ureteral stents were placed.[3] There are a multitude of studies focusing on reducing pain while the stent is indwelling, including the use of alpha blockers, anticholinergics, and narcotics.[4, 5] However, acute pain can occur for 1-24 hours after the indwelling stent is removed, substantially reducing quality of life. In our own quality improvement project at UT Southwestern we attempted to quantify quality of life metrics after URS and found that 57% of patients (12 of 21) reported experiencing renal colic after stent removal at home. Two of those patients went to the emergency department (ED) for severe pain right after stent removal that required intravenous medications.

Ketorolac is a safely and commonly used non-steroidal anti-inflammatory (NSAID) medication for acute renal colic.[6, 7] Ketorolac has also been uniquely formulated into intravesical instillations and indwelling ureteral stents for pain relief in the the post-operative period after URS. An RCT evaluated a ketorolac-loaded ureteral stent which helped reduce pain medication use in younger male patients between post-operative days 2-4.[8] No difference in pain scores after day 4 or in the number of interventions for pain were noted. In another study evaluating intravesical ketorolac instillation after stent placement showed benefit in the very early post-operative period (1 hour).[9] As ureteral stents are usually left indwelling for at least 1 week, an additional measure aimed at pain prevention is likely necessary after the acute benefits of ketorolac have worn off.

We propose an intervention by which ketorolac is administered intramuscularly immediately prior to office stent removal, effectively antagonizing pain receptors so that patients feel relief during and for at least 6 hours after removal, a time period that we have determined from our quality improvement project as the most likely time frame for patients to return to the ED. Furthermore, in regard to the recent focus of reducing opioid use, ketorolac injection will likely decrease or obviate the need for any narcotics after stent removal.

3. Concise Summary of Project:
This is a prospective randomized double-blind controlled trial assessing the benefits of intramuscular ketorolac before office ureteral stent removal. Patients who are undergoing cystoscopy with ureteral stent removal at the University of Texas Southwestern Medical Center and have no contraindications to receiving ketorolac will be eligible. Patients will be randomized to receive either a 1 mL injection of ketorolac tromethamine or 1 mL injection of normal saline (0.9%) as the control arm. Ketorolac is a member of the pyrrolo-pyrrole group of NSAIDs. The

mechanism of action of ketorolac, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. The peak analgesic effect occurs within 2-3 hours. If no contraindications exist, ketorolac can be safely given to patients of any age in the 30 mg intramuscular formulation if given as a one time dose according to the package insert (http://www.sagentpharma.com/wp-content/uploads/2016/01/Ketorolac_-PI.pdf). It is supplied in a single-dose vial which contains either 30 mg per mL or 60 mg per 2 mL. Packages come with 25 vials per carton which costs around $22 from the Aston pharmacy. It is recommended to store ketorolac at room temperature (20-25°C) and to protect from light until time of use. Unused portions should be discarded.

Normal saline contains 0.9% of NaCl in each mL (https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f2a98378-9678-4738-9670-fc7a215c0606) . Like ketorolac, it is a clear solution and given that there are no major side effects of normal saline it is a good control for our study. It is packaged in a single dose vial that contains 100 mL. It is preservative free and stored at room temperature (20-25°C). Local pain at the injection site may occur, temporarily.

4. Randomization:

After meeting inclusion procedure, patients were randomized into either the control or treatment arm. A computer-based random sequence generator was used for randomization. The allocation sequence was kept by a research nurse and concealed from the investigators and providers involved in the study. Statistical analysis was performed by a blinded investigator. Allocation was revealed after conclusion of the study.

5. Inclusion and Exclusion Criteria:

Adult patients between 18 and 80 years of age who have undergone ureteroscopy for nephrolithiasis by 2 fellowship trained surgeons (JA, MP) and placement of indwelling double-J ureteral stent(s) with or without tether at a single institution were included. Patients were required to have their stent removed in our ambulatory urology clinic. Patients were excluded if they had an absolute or relative contraindications to ketorolac. Patients with an eGFR <50, any active or history of peptic ulcer disease or gastrointestinal bleeding, bleeding disorder, suspected of confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, concurrent use of warfarin or heparin, allergic reaction to NSAIDs, concurrent use of aspiring or other NSAIDs, pregnancy, recent myocardial infarction were excluded. If patients had evidence of acute renal failure at the time of stent placement, a basic metabolic profile was be checked prior to the stent removal to ensure eligibility and safety for the study.

6. Medication Administration and Procedure:

Patients randomized to the treatment arm were given 30mg in 1mL intramuscular injection of ketorolac tromethamine immediately prior to removal of the ureteral stent in the ambulatory urology setting. Patients in the control arm were given a 1 mL intramuscular injection of 0.9% normal saline prior to stent removal. Medication to be injected was drawn up on the morning of stent removal by the research nurse in charge of the randomization sequence. Injections were performed by a different qualified registered nurse who was blinded to the medication. Stents were removed by the nurse if they were on a tether or via cystoscopy with the use of viscous

lidocaine instilled into the urethra. Patients in both arms were extensively counseled on expectations and symptoms to look for after stent removal.

7. Data Collection:
Patient demographical and surgical information was collected prospectively by a blinded investigator. Patients were then be contacted via telephone at 24 hours and 7 days following stent removal. Visual analog pain (VAS) scale, renal colic symptoms, need for narcotic medications, and instance of an unplanned pain-related clinical encounter, surgical interventions, and missed work were recorded. Unplanned pain-related clinical encounters were either ED visits or an unplanned ambulatory encounter with the urology clinic.

8. Statistical Analysis:
A student's t-test and Mann–Whitney U test was for means and medians, respectively. The chi-square test was performed for categorical variables if each category was greater than 20% of total. A Fisher's Exact Test was used for categorical variables if a category was less than 20% of total. All tests were run as a two-tailed tests and deemed significant if $p \leq 0.05$.

References

1. Scales, C.D., et al., *Prevalence of kidney stones in the United States.* Eur Urol, 2012. **62**(1): p. 160-5.
2. Ellison, J.S., M. Williams, and F.X. Keeley, *Patient-Reported Outcomes in Nephrolithiasis: Can We Do Better?* J Endourol, 2017.
3. Zhao, P.T., et al., *A Randomized Controlled Comparison of Nephrostomy Drainage vs Ureteral Stent Following Percutaneous Nephrolithotomy Using the Wisconsin StoneQOL.* J Endourol, 2016. **30**(12): p. 1275-1284.
4. Wang, J., et al., *The role of solifenacin, as monotherapy or combination with tamsulosin in ureteral stent-related symptoms: a systematic review and meta-analysis.* World J Urol, 2017. **35**(11): p. 1669-1680.
5. Wang, C.J., S.W. Huang, and C.H. Chang, *Effects of specific alpha-1A/1D blocker on lower urinary tract symptoms due to double-J stent: a prospectively randomized study.* Urol Res, 2009. **37**(3): p. 147-52.
6. Pollack, C.V., et al., *Patient-reported Outcomes from A National, Prospective, Observational Study of Emergency Department Acute Pain Management With an Intranasal Nonsteroidal Anti-inflammatory Drug, Opioids, or Both.* Acad Emerg Med, 2016. **23**(3): p. 331-41.
7. Hosseininejad, S.M., et al., *Efficacy and Safety of Combination Therapy with Ketorolac and Morphine in Patient with Acute Renal Colic; A Triple-Blind Randomized Controlled Clinical Trial.* Bull Emerg Trauma, 2017. **5**(3): p. 165-170.
8. Krambeck, A.E., et al., *A novel drug eluting ureteral stent: a prospective, randomized, multicenter clinical trial to evaluate the safety and effectiveness of a ketorolac loaded ureteral stent.* J Urol, 2010. **183**(3): p. 1037-42.
9. Beiko, D.T., et al., *Double-blind randomized controlled trial assessing the safety and efficacy of intravesical agents for ureteral stent symptoms after extracorporeal shockwave lithotripsy.* J Endourol, 2004. **18**(8): p. 723-30.

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:	Prospective randomized controlled trial for pain relief after office ureteral stent removal
Funding Agency/Sponsor:	UT Southwestern Medical Center
Study Doctors:	Dr. Margaret S. Pearle, MD, PhD, Dr. Jodi Antonelli, MD, Dr. Igor Sorokin, MD, Dr. Joseph Crivelli, MD.

You may call these study doctors or research personnel during anytime at **214-645-8765**.

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 find out whether the use of the medication "ketorolac", which is FDA approved as a nonsteroidal anti-inflammatory drug, will be useful for pain relief after ureteral stent removal. Severe pain lasting a few hours after stent removal can happen in 50% of patients. Our goal is to try to reduce that number to improve quality of life of patients who undergo surgery for stone disease.

Why is this considered research?
This is a research study because the FDA approved medication ketorolac is being compared to placebo (normal saline) in a double blind randomized fashion. While ketorolac has proven benefits with pain relief, it is being compared to a drug that has no proven benefits for pain. The researchers are interested in learning if ketorolac is more effective and/or safer than placebo in treating your condition/disorder.

The following definitions may help you understand this study:

- Double-blind means neither you nor the researchers will know which drug you are receiving.
- Placebo-controlled means that some participants 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) in one of the study groups.
- 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/will have a stent in place in your kidney that will need to be removed.

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 125 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.

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

- Pain scale questionnaire
- Quality of life questionnaire

- Demographic information (age, sex, ethnic origin)
- Blood tests

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 Ketorolac or placebo (inactive substance) You have a 1 in 2 chance of receiving ketorolac or placebo.

The group you will be in is decided by random generator. 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 this study you will receive either:

- 1 mL (30mg) injection of ketorolac intramuscularly
- 1 mL normal saline injection intramuscularly

Procedures and Evaluations during the Research
You will have the following tests and/or evaluations:

Visit 1 (office stent removal after surgery):
- You will be asked to fill out 1 questionnaire
- Injection of study drug or placebo 15 mins before stent removal
- Stent is removed and you may go home.

Phone call 1 day after office stent removal procedure:
- You will be asked to report your pain score and answer to 1 additional questionnaire over the phone
- You will be asked if there was a need for use of pain medication, emergency department visits or hospital admissions for pain

Phone call 1 week after office stent removal procedure:
- You will be asked to report your pain score
- You will be asked if there was a need for use of pain medication, emergency department visits or hospital admissions for pain, days missed from work

How long can I expect to be in this study?
The study will last for 1 week after the study drug is given.

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.

Ketorolac may cause some, all or none of the side-effects listed below.

Frequent
- Burning at injection site

Occasionally
- Upset stomach
- Nausea/Vomiting
- Diarrhea
- Constipation
- Heartburn
- Dizziness
- Headache
- Drowsiness
- Sweating
- Swelling

Serious but Rare
- Allergic interstitial nephritis
- Acute kidney injury

Because you may be in the group that receives the placebo medication you may experience severe pain after stent removal. This is common and can be addressed with strong pain medication. If pain is unremitting a visit to the emergency room may be needed. Also, it is not guaranteed that ketorolac will alleviate any, some, or all of your pain. For that reason, narcotic medication or visit to the emergency room may still be needed even if you received ketorolac.

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).

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) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon),

(3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or

(4) an intrauterine device (IUD).

If you do become pregnant during this study, you must tell the researchers immediately.

Placebo

If you receive a placebo, you will not receive active medication for your health problem. If your problem becomes worse, your participation in the research will stop. If this happens, your study doctor can discuss alternative care with you.

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?

Ketorolac is generally a very safe drug. Rarely acute kidney injury may occur which is often transient. To prevent this event from occurring you will not be included in the study if your kidney function is not adequate. Prior to administration of drug, previous lab values will be double-checked to make sure your kidney function is normal. If necessary, additional out-patient lab tests to check your kidney function after the surgery may be necessary before stent removal. This is usually routine even if you were not in 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.
- Let the researchers know if your telephone number or address changes.

- 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 be direct benefits to you including better pain control after stent removal and decreased risk of needing to go to the emergency room after removal. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others who are undergoing stent removal in the future. Information gained from this research could lead to better pain control and quality of life after stent removal.

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 the following options:
- Receiving ketorolac to prevent pain before stent removal if determined there is a high risk in your particular case for pain after the procedure

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

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.

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:

- 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.

Are there procedures I should follow after stopping participation in this research?
No.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Margaret Pearle at **214-645-8765** during regular business hours and at **214-645-8765** 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

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

Authorization for Use and Disclosure of Health Information for Research Purposes

NAME OF RESEARCH PARTICIPANT: _____

What is the purpose of this form?
This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: "Prospective randomized controlled trial for pain relief after office ureteral stent removal". Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and other others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?
University of Texas Southwestern Medical Center may use or share your health information with Dr. Margaret Pearle and her staff at UT Southwestern Medical Center ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers?
Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- The UT Southwestern Institutional Review Board (IRB). This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at UT Southwestern may review the records of your participation in this research. A representative of the IRB may contact you for information about your experience with this research. If you do not want to answer their questions, you may refuse to do so.

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

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.

How will my health information be protected?
Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT

Southwestern on this research project. There is a risk that the Recipients could share your information with others without your permission. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact being used?
Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?
The Researchers will collect pain score questionnaires, the drug you received, data related to your stone surgery and medical history, un-anticipated clinic, emergency room, or hospital visits after stent removal, use of pain medication after surgery.

Will my health information be used in a research report?
Yes, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will not include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care and a tracking code. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?
Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?
No, this authorization is voluntary. Your health care providers will continue to provide you with health care services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?
This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: Dr. Margaret Pearle MD, PhD, 5323 Harry Hines Blvd Dallas, TX 75390-9110. Tel – 214-645-8765.

Will I receive a copy of this authorization?
Yes, a copy of this authorization will be provided to you.

Signatures:

By signing this document you are permitting UT Southwestern Medical Center to use and disclose health information about you for research purposes as described above.

Signature of Research Participant	Date Time: AM/PM