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	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

APPROVAL PERIOD Sept 05, 2017 – Sept 04, 2018 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **A Randomized Controlled Trial of Oral and Intravenous Tranexamic Acid in Lumbar Spine Surgery**

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1. WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to assess if intravenous tranexamic acid is superior to oral tranexamic acid in reducing blood loss and need for blood transfusion in patients undergoing lumbar spine surgery. You will either receive intravenous or oral form of tranexamic acid prior or during the surgery.

There will be approximately 60 people in this research study at Henry Ford Health System (HFHS).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

As part of this study, you will receive either the intravenous form of tranexamic acid during surgery or the oral form of tranexamic acid prior to surgery. Your blood loss during surgery and hemoglobin levels after surgery will be measured. The dose of medications and protocols of postoperative care followed for either form are identical. You will receive similar treatments of hemodynamic monitoring and blood transfusion if necessary. This will not delay or prevent the standard post operative course after surgery. You will not need any additional follow-up beyond what is normal for back surgery. No extra labs or medications will be administered. You will receive the standard of care for back surgery, including being discharged from the hospital after clearing Physical Therapy.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. While you are in the study, you are at risk for the following side effects from the drug Tranexamic Acid:

- Likely: nausea, vomiting, diarrhea
- Less Likely: skin reactions such as rash

- Rare but serious: Anaphylactic shock (loss of blood pressure from allergic reaction), cerebral thrombosis (stroke), deep vein thrombosis (DVT – blood clots in your legs), pulmonary embolism (blood clots in your lungs), renal cortical necrosis (kidney damage), retinal artery/vein obstruction (blood clots in your kidney), seizure, ureteral obstruction (kidney stones), visual disturbances (including impaired color vision and loss)

There may be additional risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participation may include decreased blood loss and need for blood transfusions, as tranexamic acid has been shown to have those effects in cardiac, gynecological, urologic and total joint replacement surgeries. You may not directly benefit from the study, however future patients will benefit from what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

You do not need to participate in this study. Whether or not you participate in the study you will have access to the current standard of care of hemodynamic monitoring used at Henry Ford Hospital. This includes hemoglobin monitoring and blood transfusions if necessary.

You may withdrawal from the study at any time.

Talk to your doctor about your choices before you decide if you will take part in this study

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:
- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

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.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Stephen Bartol, M.D. or his staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Stephen Bartol, M.D. at (313) 461-3674. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 874-4464. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

There will be no compensation to you for your participation in this study.

13. CONSENT

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You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

COMPETENT ADULT SUBJECT

Signature of Subject	Date	Time
Print Name of Subject		
Witness to Signature	Date	Time
Print Name of Person Obtaining Consent		
Signature of Person Obtaining Consent	Date	Time