Title:

TAHFT: Evaluation of **T**ranexamic **A**cid Prior to Surgery in the Geriatric **H**ip **F**racture Population for the Reduction of Post-Operative Blood **T**ransfusion

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CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

I. STUDY INFORMATION

Title: **T**AHFT: Evaluation of **T**ranexamic **A**cid Prior to Surgery in the Geriatric **H**ip **F**racture Population for the Reduction of Post-Operative Blood **T**ransfusion

Sponsor: Louise von Hess Foundation Grant

Institution: Lancaster General Hospital
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Co-Investigators: Colin Heinle, M.D.

Protocol Number & Date: Version 1.0, 29 April 2019

II. INTRODUCTION:

Doctors may ask patients to take part in a research study. Before a patient agrees, the doctor or research staff must give the patient information about the risks and benefits of the study. The form you are about to read gives such detailed information. Once you understand the study, you can decide if you want to take part in it.

We are asking you to join a research study for people who have a hip fracture and need surgery to fix it. We want to learn if the drug tranexamic acid (TXA), given just before surgery, can reduce the need for blood transfusions. The drug helps promote blood clotting. It is approved by the US Food and Drug Administration (FDA) for other uses but not for hip fracture surgery. The risk is that TXA also could increase blood clotting that could lead to a heart attack or stroke. We want to learn if the benefits outweigh the risks for hip fracture patients. We will do this by assigning the patients in the study at random (like flipping a coin) to either get TXA before surgery or to get a placebo. Patients and surgeons will not know who got TXA. Then, we will collect data from the patients' medical records on how they are doing for 3 months after surgery. We will compare the data from the two groups.

If you join the study, you do not need to do anything extra. You just need to follow up with your surgeon for usual care.

It is your choice whether to join the study. You may refuse; it will not affect the care you receive at Lancaster General Hospital. You could still receive TXA outside of the study, depending on the choice of your surgeon. If you join the study, you will need to sign this consent form. You will receive a copy of it for your records.

III. PURPOSE:

The purpose of this study is to learn if patients who get TXA before hip fracture surgery are less likely to get blood transfusions than patients given placebo. We also want to compare how long they stay in the hospital and how many come back to the hospital within 30 days. Finally, we will compare the groups for complications from either the drug or from blood loss or blood transfusions. This will allow us to assess if the benefits of TXA outweigh the risks.

Other studies have shown that TXA reduces the need for blood transfusions in patients who have knee or hip replacements (when they don't have a fracture). We don't know if the same will be true for hip fracture patients. Hip fracture patients may have a higher risk of problems from either the drug or the surgery.

IV. NUMBER OF SUBJECTS:

The study plans to enroll 425 people here at Lancaster General Hospital.

V. PROCEDURES, LENGTH OF STUDY INVOLVEMENT, AND REQUIRED FOLLOWUP:

Your surgeon has already decided what type of surgery you need to have and has determined that you are eligible for the study. If you agree to join the study, we will use a random process (much like flipping a coin) to decide whether you receive TXA or placebo. The random process is important. It allows us to compare TXA and placebo in a fair manner (without bias). You and your surgeon will not know if you got TXA or not. Your surgery and your care after surgery otherwise will be the same as it would be if you did not join the study. You will not have any extra tests for the study. You will see your surgeon 2 weeks, 6 weeks, and 3 months after surgery for check-ups.

Your surgeon will assess how you are doing at each visit. We also will check your medical records to see if you have had any other appointments for problems that could be related to your hip surgery. If you saw any doctors outside Lancaster General or were in another hospital, it is important that you let us know. With your permission, we will get information from the other doctors and hospitals about any problems that could be related to your hip surgery.

VI. BENEFITS:

Other studies have shown that TXA reduces the need for blood transfusions with planned surgery to replace knee or hip joints. It is possible that the same may be true for hip fracture surgery. We don't know for sure, which is why we are doing the study.

VII. RISKS AND DISCOMFORTS:

Because TXA prevents blood clot breakdown, the concern is that it could cause unwanted blood clots. Such clots could lead to a heart attack, stroke, or a clot in the leg, lung, or elsewhere. Other possible serious side effects are seizure or severe allergic reaction.

Possible, less serious side effects include:

- Headache of migraine
- Myalgia (body aches and pains) and fatigue
- Anemia

- Shortness of breath or dizziness
- Hypotension
- Nausea, diarrhea, or vomiting
- Flushing or rash

It is possible there are some risks from TXA that are not yet known.

IX. ALTERNATIVES:

You do not have to take part in this study. You will still receive standard care if you are not in this study. You might even still get TXA. Whether you get TXA will be based on your surgeon's medical judgment rather than on the random process the study uses.

X. PAYMENTS AND COSTS:

Study costs will be funded by a grant from the von Hess Foundation.

There will be no cost to you for taking part in this study. You will not receive any payment for being in the study.

XI. COMPENSATION FOR INJURY OR COMPLICATION:

If you are injured because of the study, you could need medical treatment for your injuries. You or your insurance company would be responsible for the costs of that treatment.

Lancaster General Hospital does not have a program to pay for medical expenses, lost wages, lost time or discomfort for such injuries.

You do not waive any legal rights to seek compensation by signing this consent form.

XII. VOLUNTARY PARTICIPATION / RIGHT TO WITHDRAW:

Your participation in this study is voluntary. This means it is your choice whether or not to take part. You may refuse to take part in this study before you have your surgery. You will not lose benefits you would otherwise receive or suffer any penalty if you do so. You also will not jeopardize the medical care you receive from your doctor.

If you want to withdraw from the study after your surgery, you may do so. This means that we would not collect information from your medical records about how you are doing. However, because staying in the study at this time does not involve anything extra for you, we will ask you to consider allowing us to collect your data as planned.

XIII. QUESTIONS ABOUT THE RESEARCH:

If you have any questions about this research or if you believe you have been injured as a result of participating in this research study, you can contact Dr. Gregory Tocks at 717-299-4871. (See Section I for complete list of investigators and co-investigators.)

XIV. QUESTIONS ABOUT YOUR RIGHTS, COMPLAINTS OR CONCERNS:

The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at Lancaster General Health. If you have any questions about your rights as a research participant, or if you have complaints or concerns, you may send an e-mail to the HRPP (SM-HRPP@lghealth.org). You also may call the Chair of the Institutional Review Board at Lancaster General Hospital at 717-544-5091.

XV. CONFIDENTIALITY:

We will use your name and medical record number to collect information about you from your health records. We will use best research practices to keep your data confidential. Only research staff will have access to the study database where your information is stored. We will assign a study ID to you so that after the study is over, we can keep your name and other identifiers separate from the study data. If we share or publish data from the study, we will not identify you in any way.

The study data, including information about you, could be reviewed by people at Lancaster General whose job it is to make sure research is conducted properly. More information about how the research data could be used and disclosed is provided in section XVII below.

A description of this clinical trial will be available on http://www.Clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

XVI. CONSENT:

I have read the above information, or have had it read to me. I understand the purpose of the study and the possible benefits and risks of taking part in it. I have had the chance to ask questions, and all of my questions have been answered to my satisfaction. I freely give my informed consent to take part in this study.

_____	_____	_____
Patient Name (Printed)	Signature	Date/Time
_____	_____	_____
Name of legally authorized representative if applicable (Printed)	Signature of legally authorized representative ☐ *Obtained electronically*	Date/Time

_____
Relationship to Patient

_____
Representative's Contact Information (phone and/or e-mail)

_____	_____	_____
Witness Name (Printed)	Witness Signature	Date/Time

☐ *Witnessed hand-written signature*
☐ *Witnessed conversation and oral consent at time of electronic signature*

_____	_____	_____
Name of person obtaining consent (Printed)	Signature of person obtaining consent	Date/Time

XVII. HIPAA AUTHORIZATION

To conduct clinical research studies, we need to use and disclose patients' health information in several ways. The Federal law known as the Health Insurance Portability and Accountability Act ("HIPAA") requires that we get you to authorize the ways we use and disclose your health information.

A. We will obtain information about your hip fracture, surgery, relevant medical history and tests. After your surgery we will obtain information about how you are doing and any problems that you experience.
B. The researchers and the study team are the only people who will access and use your health information for study purposes.
C. We will use the data to help us learn if TXA reduces the risk of getting a blood transfusion in people who have hip fracture surgery.
D. We will not disclose your health information to anyone outside the study unless we de-identify it (remove all information that could identify you or anyone else). People whose job it is to make sure that research is being conducted properly might see your data.
E. Your permission for us to access and use your health information for the study does not expire.
F. You may refuse to authorize us to access and use your health information. If you refuse, you cannot be in the study.
G. You have the right to revoke your permission to access and use your health information for the study. You must notify us in writing if you want to do so. You cannot withdraw permission for us to use any data that we have already collected about you. If you withdraw permission, you will no longer be in the study.

I authorize my health information to be accessed, used, and disclosed as described above.

_____	_____	_____
Patient Name (Printed)	Signature	Date

For subjects unable to give authorization, it is given by the following authorized subject representative:

_____	_____	_____
Name of legally authorized representative if applicable (Printed)	Signature of legally authorized representative ☐ *Obtained electronically*	Date

_____
Relationship to Patient