SPECTRUM HEALTH

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# Permission to Take Part in a Human Research Study & HIPAA Authorization for Release of Health Information for Research Purposes

**Title of research study:** The effect of tranexamic acid on blood loss and transfusion rates in major oncologic surgery.

**Sponsor:** Spectrum Health

**Investigators:** G. Paul Wright, MD; Mathew Chung, MD; Brian Lane, MD, PhD; Andrea Wolf, MD; Christopher Brede, MD

**"You"** refers to the subject.

**"We"** refers to Spectrum Health and Spectrum Health Medical Group.

We invite you to take part in a research study because you are scheduled to undergo major surgery.

## *What you should know about a research study?*

- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

## *Who can I talk to?*

If you have questions, concerns, or think the research has hurt you talk to the investigator, Dr. G. Paul Wright, at (616) 486-6333.

This research has been reviewed and approved by the Spectrum Health Institutional Review Board. You may talk to them at (616) 486-2031 or irb@spectrumhealth.org for any of the following:

- Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or research team.
- You want to talk to someone besides the investigator or research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## *Why are we doing this research?*

Major surgery can result in blood loss that can require a blood transfusion during and/or after surgery. Tranexamic acid is a medication that was first introduced in the 1960's as a treatment for heavy menstrual bleeding. Over the past 20 years, it has been used and studied in patients undergoing open-heart surgery, liver transplantation and urologic surgery. We believe tranexamic acid may possibly decrease bleeding related to major surgery, resulting in reduced blood loss, lower blood transfusion rates and possibly decreased hospital costs related to your surgical hospital stay.

## *How long will I be in the research?*

We expect that you will be in this research study for the length of time you are in the hospital for your major surgery and for up to 90 days after your surgery.

## *How many people will be studied?*

We expect about 200 people here at Spectrum Health will be in this research study.

## *What happens if I say yes, I want to be in this research?*

- If you are scheduled for a major surgery, you may be approached about this research study by your surgeon or one of the physician residents that are doing the study with your surgeon. This may take place in your surgeon's office or in the hospital, if you are in the hospital.

- You will meet with someone from the study team from the Spectrum Health Research Department to review this informed consent with you and answer any questions that you may have. If you are interested in taking part, you will be asked to sign this consent form. This may take place at any time prior to your scheduled major surgery, but will likely take place when you come to the hospital and register on the day of your surgery.

- The pharmacy staff will be notified that you are part of this study. The designated pharmacy staff will assign you a study number, and they will be told when your surgery has been scheduled.

- In this study, you will receive either the drug tranexamic acid or placebo. The placebo looks like the tranexamic acid medicine, but does not have any active ingredient in it. In this study, both the tranexamic acid and the placebo are considered research.

- The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given the tranexamic acid or the placebo. Neither you nor the study doctor will know which treatment you are getting.

- You will receive one 1000 mg dose of either tranexamic acid or placebo immediately before surgery.

- This dose of tranexamic acid or placebo will be given in your vein over 15 minutes.

- As part of your regular care, you will continue to have your blood checked. If your blood count is low, you may require a blood transfusion, if your surgeon feels it is in your best interest.

- Information from your medical record related to your surgery and recovery time in the hospital will be collected by medical staff assisting with this study and recorded on study forms. These study forms will be labeled with your study number instead of your name. Additionally, you will be followed for 90 days from the day of your surgery. If you return to the hospital after being discharge during this time information about that hospital visit(s) will also be collect from your medical record.

- The tranexamic acid and placebo are considered experimental in this research study. All other parts of your hospital stay for your scheduled major surgery are considered part of regular care.

## *What happens if I say no, I do not want to be in this research?*

Your alternative to taking part in this study is to receive the usual medical care as prescribed by your surgeon without the study drug (either tranexamic acid or placebo). You may decide not to take part in the research and it will not be held against you. A refusal to take part will involve no penalty or loss of benefits to which you are otherwise entitled.

## *What happens if I say yes, but I change my mind later?*

You can agree to take part in the research now and stop at any time and it will not be held against you. If you stop taking part in this research, it will not result in penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the research, contact Dr. G. Paul Wright.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

## *Could being in this study be bad for me?*

By taking part in this study, you will receive either tranexamic acid or placebo. You may have side effects from the study treatments used in this study and they will vary from person to person. Following, is a list of side effects that may be caused by tranexamic acid.

<u>Risks of Tranexamic Acid:</u>

- Nausea
- Vomiting
- Diarrhea
- Dizziness

*Occasional:*

- Allergic dermatitis (skin rash)
- Giddiness
- Hypotension (low blood pressure)

*Rare:*

- Blood clotting events (blood clots in the legs, lungs, brain, kidneys, and eyes or other parts of the body)
- Convulsions
- Visual changes

You may experience some, all, or none of these side effects. However, life-threatening side effects could occur. Your study doctor does not know all the side effects that may happen and there may be unknown side effects that could occur. Side effects can vary from mild to very serious. Your doctor may provide treatment to help lessen side effects. Many side effects go away soon after you stop what is causing them. In some cases, side effects can be serious or long-lasting, cause you to be hospitalized and/or never go away. You will be monitored closely for all side effects including any that are unexpected. If symptoms develop, your study doctor will start appropriate treatment. You must tell the study doctor about any new health problems that develop while you are taking part in this study. You will be informed of any new information that could change your decision to be in this study.

Risks of Placebo

If placed in the group that will receive placebo, your risks will be minimal. The placebo in this study will look identical to tranexamic acid, but will not contain any active ingredients. Neither you, nor your study doctor will know whether you receive tranexamic acid or placebo, except in case of an emergency for further management of your care.

Possible risks related to your routine care surgery will be discussed with you by your surgeon and addressed under a separate consent form.

Under Michigan law, an HIV and hepatitis test may be done on you without your consent if a healthcare worker is exposed to your blood or other bodily fluids. If the results of an HIV or hepatitis test indicate that you are HIV or hepatitis positive, you will be told about these results and given information about the disease, treatment resources, and other options.

If you are or become pregnant during this study, there may be additional risks to you, or to your baby. Some of these risks may be known, but some risks may not be known and may not be foreseeable. Because the risks to embryo/fetus/unborn babies and babies who are breast feeding may not be known or foreseeable, pregnant women and nursing mothers are not allowed to join this study. If you are a woman who can get pregnant, you should not become pregnant during this study.

If you become pregnant during the study, you must tell the study doctor right away. It is important to tell your doctor because there may be risks to you or your baby if you continue in the study.

## *Will I need to pay for any of the tests or procedures in the study?*

The study drug, placebo and the cost to prepare and give them will be paid for by the study. All other procedures that are part of your routine care ordered by your doctor/surgeon will be billed to your health insurance company or you. If your insurance company requires any co-payment or deductible, you will be responsible for making that payment.

If your insurance is through Medicare Advantage, any routine care that is part of this study and not being paid for by the sponsor will be directed to traditional Medicare for payment. The traditional Medicare deductibles will be waived, but you will be responsible for any co-payments. Please talk to the study doctor if you have any questions about this.

## *Will being in this study help me in any way?*

We cannot promise any benefits to you from your taking part in this research. However, possible benefits include a decrease in blood loss and prevention of blood transfusion related to your major surgery. You may receive no benefit.

## *What happens to the information you collect?*

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

- The Investigator and his/her research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and staff
- Agencies that accredit the hospital or the research program
- The Food and Drug Administration (FDA)

Some of these organizations may be given direct access to your medical records for verification of the research procedures/data involved. By signing this document you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your personal information. These are described in a later section.

## *Can I be removed from the research without my OK?*

Your study doctor may stop your study involvement at any time, without your permission, if he or she believes it is in your best interest, if you do not receive the dose of study medication or if the study is stopped.

## *What if I'm injured or made sick from the research?*

If you are injured or made sick from taking part in this research study, medical care will be provided. No funds have been set aside to pay you in the event of a research related injury.

Contact the investigator for more information. By signing this consent form you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

## *What else do I need to know?*

You will not be paid for taking part in this research study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. 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.

## *HIPAA Authorization for Release of Health Information for Research Purposes*

The information we are asking to use and share is called Protected Health Information (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

## *What will be done with my information?*

Your health information will be collected and entered in a database along with the information from other people taking part in this study.

## *Why am I being asked to release it?*

Your health information will be used to determine if receiving tranexamic acid at the time of major surgery decreases blood loss or the need for blood transfusions related to the surgery. This information will also determine whether or not receiving tranexamic acid has an impact on hospital costs.

## *What will be released?*

To complete this research study, we will need to collect and release (disclose) information about you. This information may include:

- Your name, date of birth, contact information, medical record number and insurance information.
- FIN number associated with your surgical hospital stay.
- FIN number(s) associated any returns to the hospital within 90 days after you are discharged home from your initial hospital surgical stay.
- Your hospital bill for your surgical hospital stay.
- Hospital bill(s) for returns to the hospital within 90 days after you are discharged home from your initial hospital surgical stay (if any).
- Existing medical records and medical history.
- New health information collected for purposes of this study.

Personal identifiers collected on the study data forms released outside of Spectrum Health as necessary to the conduct of this research study shall be limited to dates of service for any procedures or treatments that occur during your participation in this research study.

## *Who will use it or share it?*

- The investigator and his/her research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and its staff
- The Food and Drug Administration (FDA)

Once your protected health information has been disclosed it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your protected health information may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Spectrum Health. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

## *How long will my health information be used?*

This authorization has no expiration date.

## *Can I stop my protected health information from being collected?*

You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety or make sure the research was done properly. If you have any questions about this please ask. If you want us to stop, you must tell us in writing.

If you decide to stop the collection of your protected health information for this research study, you must send a written notice to:

Dr. G. Paul Wright
145 Michigan St. NE, Suite 6274, MC317
Grand Rapids, MI 49503

Please reference the title of this research study in your written request.

## *What happens if I do not want you to collect and release my information?*

If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.

## *When will it be destroyed?*

We do not know when your information will no longer be used, therefore the information will be kept for an indefinite length of time.

## Signature Block for Capable Adult: Long Form

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

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| Signature of participant | Date | Time |
| Printed name of participant | | |
| Signature of person obtaining consent | Date | Time |
| Printed name of person obtaining consent | | |