NAVAL MEDICAL CENTER

SAN DIEGO, CALIFORNIA 92134-5000

CONSENT BY A *SUBJECT* FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION (RESEARCH) STUDY

1. You, _____, have been asked to voluntarily participate in a research project entitled, **"**Prevention of Postpartum Hemorrhage with Intravenous Tranexamic Acid (**TXA**)**"** being conducted at the Naval Medical Center, San Diego by medical researchers from the Department of Obstetrics and Gynecology.

What is the usual approach to postpartum bleeding (excessive bleeding after delivery)?

When postpartum bleeding is encountered, the delivering provider uses a combination of maneuvers, IV fluids and medications to control the bleeding. Among the medications is TXA. TXA is a non-hormonal medication that is FDA approved to treat excessive bleeding in trauma patients. It has also been used to treat postpartum hemorrhage after vaginal and cesarean delivery and before delivery in women undergoing planned cesarean deliveries.

2. WHY IS THE STUDY BEING DONE?

The purpose of this research study is to see if giving TXA through a vein in a woman's arm *BEFORE* she experiences excessive bleeding after delivery will be beneficial in *PREVENTING* excessive bleeding after delivery. Our hope is to find that TXA is effective in preventing bleeding, preventing the need for extra medications and preventing anemia that causes symptoms such as dizziness, lightheadedness or weakness due to low blood counts brought on by excessive bleeding after delivery. We hope that giving TXA will prevent the need for blood transfusions. There will be about 1,100 women taking part in this study.

3. HOW LONG WILL YOU BE PARTICIPATING IN THE STUDY?

You will be in this study until you are six weeks postpartum, and have had your postpartum visit with your provider.

Subject's Initials: _____

4. WHAT IS INVOLVED IN THE STUDY?

- You agree to volunteer to take part in the study and sign the consent.
- You arrive at Labor and Delivery when you go into active labor or are scheduled for delivery
- The nurses on Labor and Delivery will give TXA to you, using an IV, after your baby's umbilical cord has been clamped.
- Because any medication that a mother receives can get into breastmilk, we ask that mothers of babies born at less than 34 weeks/0 days throw away breast milk until 24 hours after receiving TXA.
- All babies born to mothers that take part in the study will be monitored and evaluated in the nursery and/or the NICU until discharged home.
- All mothers that take part in the study will be frequently monitored and evaluated until discharged home.
- You will see your provider as scheduled for your postpartum visit.
- You are no longer in the study once you are beyond six weeks postpartum.

5. WHAT IS THE EXPERIMENTAL PART OF THE STUDY?

The experimental part of the study is giving TXA before there is any excessive bleeding after delivery.

6. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 1,100 subjects are expected to participate in this study from the Naval Medical Center, San Diego.

7A. WHAT ARE THE RISKS OF THE STUDY?

- We do not anticipate any risks to you participating in this study other than those encountered during routine labor and delivery.
- TXA is being used in the hopes of reducing the amount of bleeding you experience and reducing your chance of having to have a blood transfusion.
- TXA will not eliminate all bleeding.
- Using TXA in this study will not guarantee that you will not have excessive bleeding or need a transfusion.
- There is always the possibility of breach of confidentiality.

Reported side effects of TXA:

Subject's Initials: _____

- Nausea, vomiting, diarrhea *may* occur, but disappear when the dosage is reduced
- Headache
- Runny or stuffy nose
- Stomach pain
- Joint or muscle pain
- Tiredness
- Dizziness

Occasionally, the following have been reported:

- A skin rash with itching
- Giddiness (laughing while being silly)
- Low blood pressure when the drug is given too fast through the vein
- Blood clots in the legs, lungs, brain, kidneys, and eyes.

7B. WHAT IF I AM OR BECOME PREGNANT?

You are being asked to participate in this study because you are already pregnant with a future date to deliver.

TXA is a "Category B" drug defined by the Food and Drug Administration (FDA) as "adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters)."

7. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your participation in this research project may be of direct benefit to you. The results of this study may help the investigators gain important knowledge about whether giving TXA can decrease postpartum hemorrhage, anemia and the need for blood transfusion.

8. WHAT OTHER OPTIONS ARE THERE?

The alternate procedure(s) or course of treatment, should you decide not to participate in this research study, has been explained to you as follows:

- You may choose to have the approach described above in "the usual approach to postpartum bleeding" section.
- You may choose not to be treated for postpartum bleeding.

Subject's Initials: _____

9. WILL I BE PAID TO PARTICIPATE?

You will not be financially compensated for your participation in this study.

10. WHAT IF I AM INJURED AS A RESULT OF PARTICIPATION IN THIS STUDY?

If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

11. WHAT ABOUT CONFIDENTIALITY?

In all publications and presentations resulting from this research study, information about you or your participation in this project will be kept in the strictest confidence and will not be released in any form identifiable to you personally. However, authorized personnel from the Navy Medical Department and from the Food and Drug Administration (FDA), where applicable, may have access to your research file in order to verify that your rights have been adequately protected.

Per 21 CFR 50.25, a description of this study may 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.

Information that identifies you will be used in this study and shared with the research staff of NMCSD only. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft, and could carry other risks affecting: ability to get insurance, current or future job status, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community, or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

PATIENT AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)

(In keeping with the Health Insurance Portability and Accountability Act)

Subject's Initials: _____

What is confidentiality of records?

Naval Medical Center San Diego makes every effort to maintain the confidentiality of protected health information we obtain about you. However, we cannot absolutely guarantee confidentiality because other people may need to see your information in the course of this research study. Most people and organizations will protect the privacy of your information, but may not be required to do so by the law. Also, if the results of this research study are presented at meetings or are published, your name will not be used.

What is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA) require that we get your permission to use protected health information about you that is either created by or used in connection with this research study. This permission is called an authorization. The information we use includes your entire research record and supporting information from your medical records, results of laboratory tests, X-rays, MRIs, CT scans and observations made by a physician or nurse which are both clinical and research in nature.

What will we do with this information?

Your protected health information will be collected and used during the course of the research study, to monitor your health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests, procedures, and commercial products.

Your research doctor will use this information to report the results of research to sponsors and federal agencies, like the Food and Drug Administration (FDA). The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

With whom will we share your information?

Your information may be shared with any of the following:

- The sponsor of the study, or its agents, such as data repositories
- Other medical centers, institutions, or research investigators outside of the Naval Medical Center San Diego, participating in this research study

Subject's Initials: _____

- State and Federal agencies which have authority over the research, the Naval Medical Center San Diego or patients. Examples are: the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Office of Human Research Protections (OHRP), the Department of Social Services (DSS) or other.
- This hospital or clinic.
- Accrediting agencies, such as The Joint Commission.
- A data safety monitoring board, if applicable
- Clinical staff who may not be involved directly in the research study, but who may become involved in your care, if it is possibly related to treatment

For this research study, the study investigators may share this authorization form and records which identify you to comply with regulatory requirements or for purposes related to this research to: all documented Principal, Associate, and Sub-investigators, and the Research Monitor (if one is assigned).

What if you want to revoke or cancel away your authorization?
If you decide to participate in this research study, your authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke your authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

Revoking your authorization only affects the use and disclosure (sharing) of information after your written request has been received. Federal law requires sending study information to the FDA for studies it regulates, like studies of drugs and devices. In a case like this, your information may need to be reported to them and cannot be removed from the research records once it is collected.

Do you have to sign this form?

You have the right to refuse to sign this authorization form and not be a part of this study. You can also tell your study doctor you want to withdraw from the study at any time without revoking the authorization to use your health information. By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above.

This authorization expires 25 years from the date of signature.

13. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding this research study, you may contact **Dr. *Maureen Farrell, Dr. Sara Drayer or Dr. Kathleen Ruzzo at 619-532-7004***

Subject's Initials: _____

If you have any questions about your rights as an individual while participating in a research study at Naval Medical Center, San Diego, you may contact **Chairman, Institutional Review Board at (619)532-9927, or John D. Malone, M.D., Head, Clinical Investigation Department at (619) 532-6099.**

If you believe that you have been injured as a result of your participation in this research study, you may contact **Naval Medical Center San Diego, Legal Department at (619) 532-6475**.

12. WHAT ARE MY RIGHTS AS A PARTICIPANT?

Your participation in this project is voluntary, and your decision not to participate will involve no penalty or loss of benefits to which you are entitled under applicable regulations. If you choose to participate, you are free to ask questions or to withdraw from the study at any time. If you should decide to withdraw from the research project, you will notify **Dr. *Maureen Farrell at 619-532-7004*** to ensure your timely removal from the study. Your withdrawal will involve no prejudice to your future health care or any loss of rights or benefits to which you are otherwise entitled. Any new significant finding developed during the course of this study, which might affect your willingness to continue participation will be communicated to you.

Subject's Initials: _____

California Experimental Subject's Bill of Rights

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

(i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Subject's Initials: _____

15. CAN I BE TERMINATED FROM THE STUDY?

The investigator may terminate your participation in this study for the following reasons:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB, or FDA.

You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

17. SIGNATURE

You are making a decision whether or not to participate in the research project above. Your signature indicates that you have had this information presented to you, have had the opportunity to ask questions about the research and your participation, and agree to participate in the study.

SIGNATURES AND **DATE** SIGNED:		**PRINTED** OR **TYPED IDENTIFICATION**:
_____		_____
Patient/Subject	(Date)	Name
_____		_____
Investigator/Researcher *(Person obtaining consent)*	(Date)	Name / Grade or Rank

Subject's Initials: _____

IRB Approval Stamp/Seal Required
(Do not make any alterations to this documents w/out prior approval)