UNIVERSITY OF WASHINGTON
CONSENT FORM for Continued Participation

A Prospective Randomized Prehospital Trial Comparing Kcentra plus Standard of Care to Placebo plus Standard of Care in Trauma Patient with Hemorrhagic Shock

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Throughout this form we use the term 'you'. If you are providing consent for a loved one, 'you' refers to your loved one.

KEY INFORMATION

You have been enrolled in a research study. Before you arrived to the hospital, medics determined your injuries were serious and potentially life-threatening. Because of this, they enrolled you in this study and started the study treatment before you got to the hospital. We will give you a separate form that describes the things that have already happened as part of the study.

The information below will help you decide whether or not you would like to continue to be in the study. Continuing to be involved in the study is voluntary. You may ask any questions about the study. Then you can decide whether or not you want to stay in the study.

PURPOSE:
The purpose of the study is to learn more about an experimental drug that may be helpful in treating traumatic injuries that may require blood products to help control or stop bleeding. Kcentra is FDA-approved, but is being used for a new, experimental purpose in this study.

DURATION:
Your continued participation in the study will consist of 6 blood draws and data collection from your medical record over the course of your hospital stay.

PROCEDURES: Your blood will be drawn (about 2 tablespoons each) at 2,12,24,48,72, and 96 hours from the time you arrived at the hospital. Some of these may already have occurred.

RISKS: There is a small chance the needle used to draw your blood will cause bleeding, a bruise, an infection, or fainting. There is also a risk of breach of confidentiality

BENEFITS: There is no direct benefit for continued participation.

ALTERNATIVES: You may choose not to continue to participate in this study.

This is a voluntary research study. You do not have to stay in the study. Even if you decide to stay in the study now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

PURPOSE OF THE STUDY

The purpose of this study is to learn about a medicine called Kcentra that may help people with traumatic injuries who may require blood products to help control or stop bleeding.

Because of your injuries, we were unable to talk to you before you were enrolled into this study. In cases where we are not able to get permission (consent), we will include the injured person in the study using a

Food and Drug Administration (FDA) approved process for emergency situations called Exception from Informed Consent Requirements for Emergency Research (EFIC).

This study will enroll 166 subjects across the United States. The study will enroll approximately 60 subjects here in the Seattle area.

STUDY PROCEDURES

If you agree to continue in this study, your medical and surgical care will not be changed.

Blood samples for research testing (about 2 tablespoons each) are collected on arrival to the hospital and at 2, 12, 24, 48, 72, and 96 hours, if you are still in the hospital at that time. The blood samples for this study will be used to look at how your blood is clotting (or clumping together). We may draw blood from an existing intravenous catheter (IV), or we may use a new needle specifically for the research.

Your hospital records will be reviewed. Information will be collected such as procedures, tests, complications and vital signs.

RISKS, STRESS, OR DISCOMFORT

You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting. We will draw blood from an existing IV whenever possible. There is also the risk of a breach of confidentiality.

There may be risks that are currently unknown. You will be informed of any significant new findings as they develop.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You may choose not to continue in this study. The study treatment was given in additional to regular treatment for traumatic injuries. If you choose not to continue participation, it will not affect your current or future care. If you do not want to continue participating in the study, contact a member of the study team and we will stop collecting further research data about you.

If you are currently/become incarcerated during your participation in this study will have no effect of your parole determinations.

BENEFITS OF THE STUDY

You may not directly benefit from this study. We cannot guarantee that there will be any benefit to you. The study may determine there is no benefit from receiving Kcentra. It is not yet known that Kcentra provides a benefit. All patients who participate in this trial will have the potential to benefit. Subjects who receive Kcentra may benefit by having bleeding controlled sooner.

SOURCE OF FUNDING

The University of Washington is being compensated by the funder (CSL Behring LLC), the manufacturer of Kcentra, to conduct this study. This is to pay for tests performed only for study purposes, and for the time involved on the part of the investigator(s) and study staff. You may freely discuss this with your physician and the investigator if you have concerns.

Your study doctor and the research staff have no financial involvement with the funder and are not being paid directly by the funder for conducting this study. However, they may have travel expenses covered by the funder to attend study training meetings.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

The investigators, study staff, and others at the University of Washington may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information (including your name) to others outside of University of Washington who are involved in conducting or overseeing research, including:

- Representatives from the Oregon Health & Science University, the Coordinating Center
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans
- An Independent Research Monitor

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

We may continue to use and disclose your information as described above indefinitely.

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.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

USE OF INFORMATION AND SPECIMENS

Commercial Profit

Samples and information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, University of Washington, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

Using Your Data in Future Research

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

The data that has already been gathered cannot be removed from the study All the information that has been collected up to the point you wish to stop your participation will be saved. If you decide to stop participating, no more information will be collected.

OTHER INFORMATION

You may refuse to stay in the study and you are free to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled,

Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs.

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed at the top of this form. This number is monitored 24 hours a day.

If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility if possible.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your traumatic injury or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to continue taking part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

When subject is not able to provide informed consent:

Printed name of representative	Signature of representative	Date

Relationship of representative to subject

Copies to: Researcher
Subject
Subject's Medical Record