UNIVERSITY OF WASHINGTON
INFORMATION SHEET

Protein-enhanced Enteral Nutrition and Metabolomics in Critically Ill Trauma and Surgical Patients
Sampling Participants Only

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RESEARCHERS' STATEMENT

We are asking you or your loved one to be in a research study. The purpose of this sheet is to give you information to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to continue to be in the study or not. We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

You or your loved one has suffered a severe injury or surgical illness. Adequate nutrition along with protein is necessary for healing and preventing complications. As part of their usual clinical care in the intensive care unit (ICU), you/they are being fed with liquid nutrition through a tube that goes into your/their stomach through the mouth or nose. This is called 'enteral nutrition'. There are many types of enteral nutrition but we do not know which is the best type to use during this critical time. As part of this research study, when you/they were started on enteral nutrition in the ICU, you/they were randomly placed in one of two groups: protein supplementation or no protein supplementation other than what is being provided via your/their enteral formula. There was a 50/50 chance of being in either group, like a coin flip. Both of these groups are standard of care here at Harborview Medical Center and both are considered safe. We just do not know if one is better than the other.

The goal of this study, which involves obtaining small amounts of blood and urine, is to examine specific elements in your/their blood and urine to help us determine what is the best nutrition we can provide to help with healing and improve overall recovery.

STUDY PROCEDURES

The duration of this study is 28 days. We have drawn and would like to continue to draw approximately 1 teaspoon of blood and collect approximately 3 ounces of urine to detect these specific elements present in the blood and urine. Blood draws and urine collection are repeated on days 1, 3, 7, 14 and 21. Usually, the blood is drawn from an IV line already required for your care. If no such IV is present, we will not draw any blood. The urine will be collected only if there is an indwelling urine catheter to collect from. We will collect the following information from your/your loved one's medical record: blood pressure, pulse, temperature, laboratory values, medications you/they are receiving, and whether there is any sign of infection or failure of your/their vital organs.

The samples of your/their blood and urine will be labeled with a code number to maintain your/their privacy.

We will use the samples to look at biomarkers, which are substances that can tell doctors and scientists about processes going on in your body. They can include proteins, small molecules, and gene transcripts in your blood or urine. These results are not used by doctors as part of your medical care and will not be shared with you.

RISKS, STRESS, OR DISCOMFORT

Although we will make every effort to protect your privacy and confidentiality, it is possible that your involvement in the study could become known to others. To minimize this risk, the information that we collect about your or your loved one's medical history and hospital stay will be kept strictly confidential. All identifiers (name and hospital number) will be removed from all of the blood and urine samples before they are sent to our research lab. A code number will be assigned to you/them and only the investigators here at Harborview Medical Center will be able to link your/your love one's specimens to you/them. The link between your/their identifier and the research data will be destroyed after the records retention period required by state and/or federal law.

There is a small risk of infection or discomfort when the blood is drawn from the IV that is already in place.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Being in this study is voluntary. You or your loved one does not have to give blood or urine samples if they do not want to participate in this part of this study. You/they can stop giving samples at any time and it will not affect your/their health care.

BENEFITS OF THE STUDY

You or your loved one will not benefit from being in this research study. However, society may benefit if the results from this study lead us to a better understanding of how to provide adequate nutrition during this critical time.

SOURCE OF FUNDING

The study team and/or the University of Washington and is receiving financial support from the National Institute of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information we collect about you will be kept confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The research staff will protect your data from disclosure to people not connected with the study.

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.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;

- individuals at the University of Washington, the funding agency, and other groups involved in the research;
- if they need the information to make sure the research is being done correctly;
- if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

Being in this study is completely voluntary. Let the researchers know if you want to be in the study, or if you would like to stop being the study.

If your blood, urine, and medical record information has already been collected and you do not want to be in the study, you can ask researchers to not use your information in the study. It will be destroyed along with the rest of the study records and specimens at the end of the study.

We would also like share some of the information that we have collected in this study with other members of the scientific community. The data will have identifying information on it. If you would like to withdraw your data or samples from being used for other research, please call us at 206-744-7723 or write to Laura Hennessy, RN at hennessy@uw.edu

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Dr. Grant O'Keefe, MD; 206-744-2359.

If you have any questions about participating in the study, ask the researchers. If you have questions later about the research, or if you have been harmed by participating in this study, you can contact one of the researchers listed on the first page of this consent form. If you have questions about your rights as a research subject, you can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.