DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

(If you are the legal representative signing this document for a patient who is unable to provide consent, the word "you" refers to the patient. If, during the course of the project, the patient regains the ability to make decisions he/she will be asked to read this consent form and decide whether to continue participation.)

CONCISE SUMMARY

This is a research study to develop a noninvasive test using ultrasound to determine when urgent, life-saving treatment is needed for those with a severe traumatic brain injury.

If you agree to participate in this study you will have ultrasounds of your optic nerve, the nerve that connects your eye to the brain. The ultrasound probe will be placed on your eye for this study. These ultrasounds are being done for research purposes only. The results of these ultrasounds will not be used to make any decisions about your medical care. The ultrasounds will be done in succession. In addition, we will collect your clinical information throughout your hospitalization.

The ultrasound images will be obtained in two sessions. Once while the pressure in the brain is high and once when it is low. At each ultrasound session the eye may be ultrasounded twice with different machines. We may repeat the ultrasound another time if the quality of the image is low.

The risks of ultrasound are pressure from the ultrasound probe that may cause some discomfort. There are risks related to loss of confidentiality, but every effort will be made to safeguard your information.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you may have a traumatic brain injury.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

If you are currently taking part in another research study, please tell the study doctor or study staff at this time.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

A grant from the United States Department of Defense awarded to the company Kitware, will sponsor this study. Kitware is a company that specializes in open source software platforms. Duke is collaborating with Kitware on this research. The computer formula being studied was developed by Duke and Kitware. Portions of Dr. Sean Montgomery and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Sean Montgomery will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The most common currently used method for measuring intracranial pressure (pressure around the brain) is through the placement of a catheter, called an external ventricular drain (EVD) into the skull. This is an invasive procedure and requires intensive care resources. Therefore it cannot be performed outside of a hospital environment.

In this study, we want to develop a noninvasive method to measure bleeding and pressure around the brain in a non-hospital setting. This will be done with the use of ultrasound and development of a computer formula that would allow medical personnel in the field to determine when urgent, life-saving treatment is needed for patients who may have a traumatic brain injury.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 120 people will take part in this study at Duke, including 80 patients with traumatic brain injury.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will have ultrasounds done of your optic nerve, the nerve that connects your eye to your brain. Your eye will be closed and covered with a sterile dressing. The ultrasound probe will be placed on your covered eye for this study. These ultrasounds will not delay any treatment that you may require. At each ultrasound session, the eye may be imaged with two different probes, the device that measures ultrasound frequency to create images. . All ultrasound machines and probes are FDA approved. The computer formula being developed with it is considered investigational. "Investigational" means that this computer formula is being studied is not FDA-approved. However, the investigational formula will not be used to make decisions on your care. The investigational software will not be used at your bedside, but later in a lab.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

We will plan to perform two ultrasound sessions, one when the intracranial pressures are high and one when they are normal (lower). We will monitor your progress for up to 5 days while you are in the hospital. If there is a change in your intracranial pressure (pressure inside your skull) the ultrasounds will be repeated.

We will collect your clinical information throughout your hospitalization. This includes information such as your demographics (height, weight, age, gender), medical history, diagnosis, and information about any treatment you receive. We will also review any available imaging done as part of your routine care for injury to your brain.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to be in this study, your active participation will be up to 5 days. We will continue to follow your progress throughout your hospitalization, and your participation may last up to two weeks after you are discharged to allow for data collection. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
During the ultrasound procedures, the handheld wand is placed on the skin and pressed down in order to get images of the inside of the eye. This could result in some pain if you are already experiencing pain, but will not cause any damage to your eye. The staff will try prevent any pain you may have by not pressing the wand too firmly against your skin. If you have pain from having the ultrasound, the procedure will be stopped. The ultrasound procedure will be performed only on an eye that is obviously without recent injury.

There is a risk of loss of confidentiality of your private information. Every effort will be made to protect your information, but this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are no direct medical benefits to you for participating in this study. Information collected may improve the detection and treatment of patients with traumatic brain injury in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be shared if required by law.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

As part of the study, you will be asked to have four ultrasounds performed. The results of these tests will not be used to make decisions about your medical care and will not be included in your medical record. They will only be used for the purposes of completing this research. Copies of your ultrasound images will be shared with Kitware and collaborators outside of Duke for review to see if adjustments to the computer formula are needed. No data that can directly identify you will be included on the ultrasound images that are shared outside of Duke.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the United States Department of Defense, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some recipients who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs associated with your participation in this study.

WHAT ABOUT COMPENSATION?
You will not be compensated for participating in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a direct result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Montgomery at 919-681-3784 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask that he be paged.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that has already been collected for study purposes, and any new information about an adverse event related to the study, will be maintained.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw from the research study, we ask that you contact Dr. Montgomery in writing and let him know that you are withdrawing from the study. His mailing address is DUMC Box 2837, Durham, NC, 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your study doctor may decide to take you off this study if he determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ct2/home 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Montgomery at 919-681-3784 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask that he be paged.

For questions about your rights as a research participant, to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Subject

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____
Printed Name of Person Obtaining Consent

"As the representative of the subject, I am acting on behalf of the subject and am aware of no factor that would be considered to create a conflict of interest (such as a potential independent personal benefit) for me in consenting to the subject's participation in this study."

_____ _____ _____
Signature of Legal Representative Date Time

_____
Printed Name of Legal Representative

_____
Relationship to Subject

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients

TBI Patient Consent Form

"Having regained the ability to make decisions for myself, the purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to continue to participate in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject (for re-consenting)	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time