How can I share my opinions about this study?

Before the study starts, meetings will be held in the community to provide information, answer questions, and get community members' thoughts and feelings about the study. You can call the study team to complete a one-on-one interview or survey about the study. There will also be information about the study in the media (for example, newspapers, TV, and radio).

What if I do not want to be included in the study?

If you decide you don't want to be included in the event you suffer a future TBI, contact us to request an Opt Out medical alert bracelet be sent to you to wear with the words "BOOST3 declined". Wearing this medical alert bracelet at all times throughout the study period (about 5 years), is your way of communicating your wishes in case you suffer a severe TBI and are unconscious. If you do not participate in the study, you will receive the standard medical treatment provided for traumatic brain injuries at the hospital in your community.

Where can I learn more about this study?

Online at: boost3trial.org
Or if you would like to know about a community meeting near you or to get more information about BOOST3, contact a local study team member (on the back).

SIREN Network

The BOOST3 study is part of The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN). SIREN is funded by the National Institutes of Health, an agency of the federal government.

SIREN seeks to improve the outcomes of patients with neurologic, cardiac, respiratory, hematologic and trauma emergencies by identifying effective treatments administered in the earliest stages of critical care.

The SIREN Network funds 13 institutions across the country to coordinate and enroll subjects at many additional hospitals. About 45 hospitals will participate in BOOST3. The hospitals participating in BOOST3 in this area include:

- Cooper University Hospital
- Thomas Jefferson University Hospital
- University of Pennsylvania
- Temple University Hospital

Contact Us

BOOST3 Study
University of Pennsylvania
Penn Presbyterian Medical Center
51 North 39th Street
Philadelphia, PA 19104
Phone: 215-662-8924
E-mail: TBIResearch@uphs.upenn.edu

BOOST-3

BOOST-3

Learn about a study of emergency care in patients with severe traumatic brain injury.

This study that may affect you or someone you know.

A research study conducted by
The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN)

boost3trial.org

What is TBI?

Traumatic **B**rain **I**njury **(TBI)** is sudden damage to the brain caused by an outside force to the head – such as a car crash, a fall, or something hitting the head.

- Every 15 seconds someone in the US suffers a major TBI.
- Every five minutes someone is forever disabled as a result of TBI.
- TBI is the leading cause of death and disability in children and adults 1-44 years of age.

TBI can affect a person's ability to think and remember things, cause problems with balance and coordination, prevent a person from functioning independently, cause permanent brain damage or even death.

What is BOOST3?

BOOST3 is a research study to learn if either of two strategies for monitoring and treating patients with TBI in the intensive care unit (ICU) is more likely to help them get better. Both of these alternative strategies are used in standard care. It is unknown if one is more effective than the other. In one strategy doctors concentrate only on preventing high ICP (intracranial pressure) caused by a swollen brain. In the other strategy doctors try to prevent high ICP, and also try to prevent low PbtO2 (brain oxygen). It is unknown if measuring and treating low brain oxygen is more effective, less effective, or the same as monitoring and treating high brain pressure alone. The results of this study will help doctors discover if one of these methods is more safe and effective.

Who will be included?

- People who are 14 years or older with a
- Blunt closed head injury, with
- Severe brain injury, and
- Can start the study immediately following brain monitor placement.

People who meet the entry criteria will be randomly entered, like flipping a coin, into one of the two study groups:

- Those that get medical care based on monitoring of pressure in the brain (intracranial pressure or ICP) alone.

- Those who get medical care based on both ICP and the amount of oxygen in the brain (brain tissue oxygen or PbtO2).

What are the benefits?

Because we do not know which treatment is best for treating TBI, a person enrolled in the study may benefit from being placed in one study group over the other. Based on the information we get from this study, people who have a TBI in the future may benefit from what is learned from this study.

What are the risks?

The different treatment strategies may affect:

- Risk of pneumonia or lung injury
- Severe infection in the blood or brain

Brain probes may involve risks of

- Bleeding or infection

Risks of participating in research include:

- Breaches of confidentiality

How is enrollment in BOOST3 different from other studies?

Normally, researchers get permission (consent) before a person can be included in a study. A person with a severe TBI will not be able to give consent at the time of injury. Since TBI must be treated quickly, there might not be enough time to locate and talk to the person's family or legal representative about the study. The strategies being studied typically need to start within 2 to 10 hours of injury. When consent is not possible, a person might be enrolled in this study without consent. This is called "**E**xception **f**rom **I**nformed **C**onsent" (**EFIC)**. Once the family or legal representative is located, they will be asked whether they want the participant to continue in the study.

What is EFIC?

Exception from informed consent (EFIC) for emergency research refers to a special set of rules used by the US government to regulate studies when research participants cannot tell researchers their desires in a medical emergency. These special rules allow research studies in certain emergency situations to be conducted without consent.

EFIC can only be used when:

- The person's life is at risk, AND,
- The best treatment is not known, AND
- The study might help the person, AND
- It is not possible to get permission:
  - from the person because of his or her medical condition nor
  - from the person's representative because there is a very short amount of time required to treat the medical problem, or the representative is not available.