

# For the Greater Good, Please Share your Brain with Us

Special considerations in traumatic brain injury and emergency medical research

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You just got hit by a car on your bike. You're unconscious and your brain is bleeding. Medics arrive to help you, see that you have a traumatic brain injury, and agree that you have the right injury to participate in a University of Washington study to improve survival and function after a traumatic brain injury. The medics see that no one else you know is on the scene who can express your wishes and that you aren't wearing a wrist band telling them you don't want to be in the study. They enroll you in the study. Based on the study procedure you may get the standard treatment or the study treatment—only the code on the medicine knows which one, and the medics record the code. After you are admitted to Harborview Medical Center, research staff will tell you and your family about the study and request consent for continued participation.

Are you comfortable with this research in Seattle? Would you want to opt out in the event you experience a traumatic brain injury?

## Key facts about the planned national study at Harborview

- For trauma patients aged 40 and younger, traumatic brain injury is a leading cause of death
- More than 1.6 million people each year have brain injuries with 52,000 deaths and 80,000 permanent disabilities
- Has been approved by the Food and Drug Administration (FDA), Department of Defense, National Institutes of Health and the University of Washington Institutional Review Board (a body whose job is to protect human research participants)
- Goal is to determine whether a medicine, tranexamic acid (TXA), increases immediate survival and brain function as measured 6 months after the traumatic brain injury (TBI)
- Medicine already approved by FDA for use in treating internal bleeding and is commonly used in trauma patients and on the battlefield
- Is one of 10 study hospitals in the USA and Canada
- Will enroll about 100 people in the Seattle area
- For local brain-injured people aged 15 and up, unless parents object
- Study is funded by the U.S. Department of Defense and the National Institutes of Health
- Study is conducted under the federal regulations for Exception from Informed Consent in an Emergency Setting

## What is informed consent and why is it important?

Informed consent means that a person participating in a research study is entering the study with their eyes wide open and they are volunteering to participate. If people participate in medical research, they should understand

- their rights as research participants;
- what their participation means for them (and maybe their family or community)-risks, discomforts, benefits, time costs
- if there are any alternatives to participating, such as standard medical treatments or doing nothing
- whether they will receive money
- whether and how they will get treatment and/or money in the event they experience a research injury
- that their participation is confidential
- that participation is voluntary
- who to talk to if they have questions about the study

Informed consent is important because

- It shows respect for each person who volunteers
- It is a process that helps people think through whether participation is right for them
- It is a process that helps the research team put themselves in the participants' shoes

If informed consent is so important, why can the IRB approve an exception for emergency research (from 21CFR50.24\*)?

- person is in a life-threatening situation
- person cannot give informed consent because of their injury
- person's legal representative cannot give consent within necessary therapeutic timeframe
- person may directly benefit by being in the study
- possible risks are reasonable considering possible direct benefits, demonstrated by previous research
- person, or person's legal representative, is informed as early as possible about study participation and allowed to discontinue study if desired
- the community is consulted and the public is informed about the study before it starts

### Questions for discussion at tables

1. What should be the balance between autonomy, that is, the right of a person to determine his or her own future, and emergency research that benefits the larger community? Is it just to deny the opportunity for new treatments from these kinds of studies?
  - a. Who are the stakeholders?
  - b. How might different stakeholders benefit and at whose cost?
2. Can public disclosure be effective for studies like this with an informed consent exception for emergency research? How can many people be reached with information about the proposed study?
3. Do you have any concerns about this study? What excites you about this study?
  - a. Can most at-risk people be informed about opt-out options?
  - b. Will people think they will still get the best care if they opt out?
  - c. How could the study results improve treatments for traumatic brain injury?

## Readings and Resources

- Study website: <http://www.uwmedicine.org/harborview/services/trauma/txa>
- Clinical trials.gov: <https://clinicaltrials.gov/ct2/show/NCT01990768?term=tranexamic+acid&rank=50>
- KUOW/NPR interview about exception from informed consent studies with bioethicist Arthur Caplan  
<http://kuow.org/post/ethical-question-medical-research-without-consent>
- Sound Medicine on NPR aired interview with Dr. Bulger  
[http://www.npr.org/rss/podcast/podcast\\_detail.php?siteId=4819624](http://www.npr.org/rss/podcast/podcast_detail.php?siteId=4819624)
- UW NewsBeat article: <http://hsnewsbeat.uw.edu/story/ga-discusses-trauma-study-exemption-consent-laws> and related YouTube video: [http://youtu.be/\\_gtZmmT2dg](http://youtu.be/_gtZmmT2dg)
- Studies using tranexamic acid <http://www.biomedcentral.com/1471-227X/13/20> and  
<http://www.bmj.com/content/343/bmj.d3795>
- [http://seattletimes.com/html/localnews/2024022734\\_noconsentstudyxml.html](http://seattletimes.com/html/localnews/2024022734_noconsentstudyxml.html)
- \*21CFR50.24 is the US Food and Drug Administration's Code of Federal Regulations, Title 21, Part 50-  
protection of human subjects, Section 50.24-Exception from informed consent requirements for  
emergency research <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24>

## Other Resources

KOMO: <http://www.komonews.com/news/local/Harborview-drug-study-raises-ethical-dilemma--266528671.html?tab=video&c=y>

KIRO: <http://www.kirotv.com/news/news/harborview-test-drug-unconscious-patients/ngcB4/>

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