Harborview Medical Center
Summary Report of Community Consultations
The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN)

This is a report of findings from community consultations regarding a clinical trial that can only be performed with exception from informed consent for emergency research. Community consultations were performed pursuant to 21 CFR 50.24, related regulatory guidance documents, and the Advarra approved EFIC plan.

The report consists of a two page overview of the findings, and then additional pages including further descriptive statistics of the community consultation (CC) events and more detailed descriptions of the feedback provided by participating community members.

Trial **Brain Oxygen Optimization in Severe Traumatic Brain Injury—Phase 3**

NIH # U01 NS099046 ClinicalTrials.gov ID NCT03754114

The SIREN Clinical Coordinating Center has confirmed the following EFIC Plan Criteria has been met:

1) At least 6 total CC events

2) At least 2 events from column A: A presentation at an existing group, Focus group, A PI staffed booth or table event involving an interactive discussions, A convened meeting with a RSVP

3) At least 1 event from column B: Delegated telephone or in person interview/survey, Web-based survey, Interactive social media event, Non PI staffed booth event.

Report Date: Jul 31, 2019

This report includes findings from community consultation events that took place between Mar 27, 2019 and May 25, 2019. It includes findings from 12 events/activities reported by 1 BOOST3 site. These events involved 697 participants in the consultation process. Guidance documents suggest that community may be defined geographically or by orientation to the specific condition or disease being studied. Of the reported events, 42% involved a geographic community, 0% a condition-oriented community, and 58% involved both. Of all participants 654 provided feedback including 3567 answers to closed ended questions and 59 open ended comments. Among responses expressing an opinion 90% of closed ended and 77% of open ended comments were supportive.

Overview

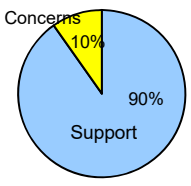
Number of Hubs reporting:	1
No. of activity reports:	12
No. of participants:	697
Types of community involved	
Percent geographic community:	42%
Percent condition-oriented community:	0%
Percent both types of community:	58%
Type of consultation activities	
A: Presentation w/ an Existing Group	33%
B: In-person Survey/Interview	17%
A: PI staffed Booth Event	50%
A: Focus Group	0%
A: Convened Meeting w/ RSVP	0%
B: Non-PI staffed Event	0%
B: Electronic Survey (not social media)	0%
B: Telephone Survey	0%
B: Social media Event	0%

Participant Demographics

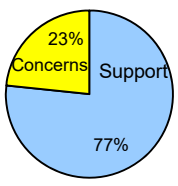
Age (average)	49 years
Female	53%
Male	47%
Race	
White	51%
Black/African American	17%
Asian	17%
Other race	0%
American Indian or Alaska Native	6%
Native Hawaiian or Pacific Islander	9%
More than one race	1%
Ethnicity	
Hispanic/latino	19%
Non-hispanic	81%

Feedback Summary

# of individual survey respondents	654
Total # of closed ended responses	3,567
Total # of open ended comments	59



Closed Ended Responses
Expressing Opinion
n= 3350



Open Ended Comments
Expressing Opinion
n= 30

Overview (continued)

Intended event audience		intended audience versus community type (number of events)	
		geographic	condition-oriented
General/geographical community	8%	1	1
Healthcare professional	8%	1	0
High risk specific	42%	5	0
Informal leader	0%	0	0
Formal leader	0%	0	0
Ethnic/racial community	8%	1	0
Age specific	33%	4	0
Parent	0%	0	0
Other	0%	0	0

totals events may be greater than 12 because some events included both community types

Detail on types of community consultation activities

	no. of events	no. of participants
A: Presentation w/ an Existing Group	4	106
B: In-person Survey/Interview	2	228
A: PI staffed Booth Event	6	363
A: Focus Group	0	0
A: Convened Meeting w/ RSVP	0	0
B: Non-PI staffed Event	0	0
B: Electronic Survey (not social media)	0	0
B: Telephone Survey	0	0
B: Social media Event	0	0

Detailed View of Individual Events

Site	Date	Name of Event	Type of Consultation	Number of Participants	Participant Average Age
Harborview Medical Cente	04/17/19	The Mountaineers Educational Series	A: Presentation w/ an Existing Group	17	43.6
Harborview Medical Cente	03/27/19	Harborview Research Day	A: PI staffed Booth Event	74	34.0
Harborview Medical Cente	04/27/19	Brain Injury Alliance of Washington: Walk, Run and Roll	A: PI staffed Booth Event	112	41.6
Harborview Medical Cente	05/11/19	Renton Bike Rodeo and Safety Fair	A: PI staffed Booth Event	45	32.4
Harborview Medical Cente	04/23/19	Keep your balance, keep moving class	A: Presentation w/ an Existing Group	12	74.2
Harborview Medical Cente	05/01/19	Fall prevention class	A: Presentation w/ an Existing Group	15	78.2
Harborview Medical Cente	04/28/19	Headstrong for Life: Adaptive bicycle Day	A: PI staffed Booth Event	23	48.0
Harborview Medical Cente	05/01/19	Lazarus Center, Homeless day care	B: In-person Survey/Interview	200	74.0
Harborview Medical Cente	04/23/19	KentHope Day Center and Shelter	B: In-person Survey/Interview	28	42.0
Harborview Medical Cente	04/26/19	Line Dancing and Fitness at Filipino Senior and Family services Center	A: Presentation w/ an Existing Group	62	57.0
Harborview Medical Cente	05/22/19	University of Washington booth	A: PI staffed Booth Event	63	23.0
Harborview Medical Cente	05/25/19	Farmer's market table	A: PI staffed Booth Event	46	42.0

Goals of the EFIC Plan

The CC/PD activities performed met the goals set in the BOOST EFIC plan.

Specifically, the activities showed respect for persons by: seeking and engaging in meaningful dialog about the study. talking to people in their environment reaching out to people during community life We ensured that the activities provided a means for affected communities to provide input by: meeting with people of all ages (college to seniors), backgrounds (socio-economic), race, ethnicity and medical risk and experience. meeting with patient groups, clinical groups. We attended events that are attended by a diverse cross section of the community like the bike safety fair, the various senior groups and the Farmer's Market.

We showed respect for communities by engaging with representatives from local civic organizations. We showed respect for individuals who have, or may be at greater risk for TBI by presenting study to mountain climbers, athletes, brain alliance association and seniors. We also left flyers in locations visited by this population (head injury clinic and support group).

The take away messages from our CC/PD: the population generally favors EFIC research and the majority of those learning about the study would be willing to participate if they suffered a TBI. The concerns we heard were relatively infrequent and mostly involved transparency.

Event Narrative Summary

Name of Event	Description of Event
The Mountaineers Educational Series **A: Presentation w/ an Existing Group**	Study PI was a guest speaker at this regularly scheduled group meeting. Participants comprised of mountain/rock climbing club. Socio-economic, age, race and ethnicity equally represented. Following a 30-minute talk about recognizing head injury in the “back country” the study was introduced and details were presented using the CC short slide show. Discussions following presentation were supportive of research. Questions asked: • Can you give a bit more detail about the background for this research? • Does the brain tissue oxygen probe need extra hole or procedure to insert? Participants were asked to complete a survey and asked to return it when leaving. Oral comments during discussions were documented by study staff.
Harborview Research Day **A: PI staffed Booth Event**	This is an annual event at Harborview Medical Center which enables the ICU nursing staff to learn about past, present and future research studies occurring in their units. Table with a poster advertising the study was set up in break room in the Trauma ICU. ICU staff were able to stop by each table, discuss projects and ask questions. 10-15-minute presentations about study was done with small groups (3-5). BOOST3 study Synopsis was used as a guide during presentations. Participants were generally women with diverse Race and Ethnicity. Many were parent of a child who would be eligible for enrollment. Discussions following presentation were supportive of research. Questions asked: • How will this impact standard care currently provided? • What will I be asked to do to assist in this project? • Is someone available to discuss study with family? Participants were asked to complete a survey and asked to return it when leaving or return via hospital mail. Oral comments during discussions were documented by study staff. Many study brochures were distributed.
Brain Injury Alliance of Washington: Walk, Run and Roll **A: PI staffed Booth Event**	This was a fund-raising event (5k walk, run, roll) for the Washington Brain Injury Alliance. Participants composed of former TBI, families of TBI and community supporters. Socio-economic, age, race and ethnicity equally represented. Table with a poster advertising the study was set up prior to event. Study team member presented the study information to small groups of 5-6 followed by Q&A and comments. Conversation continued during the 5K walk. Oral comments recorded by study team member. Discussions were all supportive of research, especially for TBI. Many related personal stories of TBI. Questions asked: • What defines standard of care? • Will “unblinding” occur if clinically necessary? Participants were encouraged to either complete a survey during the event or to go to website and complete the on-line survey. Study brochures were distributed.
Renton Bike Rodeo and Safety Fair **A: PI staffed Booth Event**	This event included activities for children ages 4-12 to teach and promote bicycle safety. The target audience at this event were parents. Table with a poster advertising the study was set up and staffed by study team member. 10-15-minute presentations about study was presented to small groups (3-5) as they attended the bike fair. Socio-economic standing, Race and Ethnicity were diverse. BOOST3 study Synopsis was used as a guide during presentations. Following presentation, conversation was encouraged. Study team member documented oral comments. Several parents voiced appreciation for the information and for including their opinions. Question asked: • Does 2 numbers mean 2 holes? Participants were encouraged to either complete a survey during the event or to go to website and complete the on-line survey. Study brochures were distributed.
Keep your balance, keep moving class **A: Presentation w/ an Existing Group**	Study staff attended the class. This facility hosts daily senior events. Table with a poster advertising the study was set up following the event. Following a brief introduction, the study was discussed. The BOOST3 study Synopsis was used as a guide during presentation. The participants were all seniors representing diverse socio-economic and ethnic backgrounds. Following the presentation, conversation was encouraged. Discussions were all supportive of research. Few questions were asked: • If both ”treatments” are standard why do you need permission? • Is this treatment used in stroke? Oral comments documented by study staff. Participants were asked to complete a survey and return it prior to leaving. Study brochures were distributed.
Fall prevention class **A: Presentation w/ an Existing Group**	This was a scheduled regularly occurring event. This facility hosts daily senior events. Table with a poster advertising the study was set up following the event. Following a brief introduction, the study was discussed. The BOOST3 study Synopsis was used as a guide during presentation. The participants were all seniors representing diverse socio-economic and ethnic backgrounds. Following the presentation, conversation was encouraged. Discussions were all supportive of research. Few questions were asked: • What happens if the doctor wants to see both values? Oral comments documented by study staff. Participants were asked to complete a survey and return it prior to leaving. Study brochures were distributed.

Name of Event	Description of Event
Headstrong for Life: Adaptive bicycle Day **A: PI staffed Booth Event**	This was an adaptive bicycle event sponsored by Head Strong for Life. Participants composed of former TBI, families of TBI and community supporters. Socio-economic, age, race and ethnicity equally represented. Table with a poster advertising the study was set up prior to event. Study team member presented the study information to small groups of 5-6 followed by Q&A and comments. Oral comments recorded by study team member. Discussions were all supportive of research, especially for TBI. Many related personal stories of TBI. Participants were encouraged to either complete a survey during the event or to go to website and complete the on-line survey. Study brochures were distributed.
Lazarus Center, Homeless day care **B: In-person Survey/Interview**	The Lazarus Center provides day shelter and overnight facilities for homeless and marginally housed men and women age 50 and older. Table with a poster advertising the study was set up in dining room area at lunch. This was staffed by study staff. 10-15-minute presentations about study was presented to small groups (5-8) as they arrived for lunch. Participants were men and women age 50 and up with diverse Race and Ethnicity. BOOST3 study Synopsis was used as a guide during presentations. Following presentation, conversation was encouraged. Discussions were all supportive of research with only a few not sure about EFIC. Few related stories of themselves or family with TBI. Several spoke of their appreciation being included in the EFIC process. Few questions were asked: • Will I receive the same care? I want the doctor to do what is best. • Is this only at Harborview? Participants were asked to complete a survey and asked to return it when leaving lunch. Oral comments during discussions were documented by study staff. Many study brochures were distributed.
KentHope Day Center and Shelter **B: In-person Survey/Interview**	Table with a poster advertising the study was set up in dining room area at lunch. Facility serves as a day center to women and children providing shelter, meals, health care and classes. 10-15-minute presentations about study was presented to small groups (5-8) as they arrived for lunch. BOOST3 study Synopsis was used as a guide during presentations. Following presentation, conversation was encouraged. Discussions were all supportive of research with only a few not sure about EFIC. Few related stories of themselves or family with TBI. Several spoke of their appreciation being included in the EFIC process. Few questions were asked: • Explain why you cannot ask before enrolling (EFIC clarification) • Will I receive the same care? I want the doctor to do what is best. Participants were asked to complete a survey and asked to return it when leaving lunch. Oral comments during discussions were documented by study staff. Many brochures distributed.
Line Dancing and Fitness at Filipino Senior and Family services Center **A: Presentation w/ an Existing Group**	Study staff attended the line dancing class and lunch meal. This facility serves as both a senior and family center for the Filipino community of King County, WA. Following brief introduction, the study information was presented using approved slides. BOOST3 study Synopsis was used as a guide during presentations. A Filipino interpreter was used during presentation and during Q&A and comments. The participants were mainly seniors, along with some parents with children. Following presentation, conversation was encouraged. Discussions were all supportive of research. Few questions were asked: • Will I receive the same care? I want the doctor to do what is best. • If both ”treatments” are standard why do you need permission? Oral comments documented by study staff. Participants were asked to complete a survey and return it when leaving lunch. Study brochures were distributed.
University of Washington booth **A: PI staffed Booth Event**	Table with a poster advertising the study was set up outside of main dining hall on campus of University of Washington. This was staffed by a study team member. 10-15-minute presentations about study was presented to small groups (5-8) as they arrived for lunch. Majority of participants were college students (age 17-28) and a few faculty/employees (age 32-58). Race and Ethnicity was diverse. BOOST3 study Synopsis was used as a guide during presentations. Following presentation, conversation was encouraged. Discussions were all supportive of research with only a few not sure about EFIC. Many had friends/family who had suffered a TBI. Few questions were asked: • clarification of enrollment criteria (what constitutes traumatic brain injury) • Can I be enrolled if my parents live in another country • Who is paying for this study • Where can I get additional information Participants were asked to complete a survey and either return it when leaving lunch or to return using a drop-box on campus. Oral comments during discussions were documented by study staff. Many study brochures were distributed.

Name of Event	Description of Event
Farmer's market table **A: PI staffed Booth Event**	Table with a poster advertising the study was set up at Pike Place Farmer's Market. This venue sees a large volume of foot traffic both local and tourists. 10-15-minute presentations about study was presented to small groups (3-5) as they visited the market. BOOST3 study Synopsis was used as a guide during presentations. Following presentation, conversation was encouraged. Few questions were asked: • What if I wake up and don't want to be in study? • Should I tell my (family) doctor/family that I want to participate now? • I don't live in Seattle, where else is this study occurring? Study staff documented oral comments. Most were in favor of research but some did not like not being asked first. Distributed study brochures and encouraged participants to go to website and complete the on-line survey.

# indicates questions for which "strongly agree" or "agree" are coded as supportive and in which "strongly disagree" or "disagree" are coded as concerned
* indicates questions for which "strongly agree" or "agree" are coded as concerned and in which "strongly disagree" or "disagree" are coded as supportive

Questions (in descending order by the number of respondents)	**Yes** or **Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**No** or **Strongly Disagree**		Number of Respondents
BOOST3 is an important study to do.	64%	18%	13%	5%	0%	#	654
	421	116	84	33	0		
If you had a traumatic brain injury, you would be okay with being included in BOOST3 without first giving your consent ahead of time.	63%	16%	15%	6%	0%	#	570
	357	92	86	35	0		
If you are/were a parent, and your child had a traumatic brain injury, you would be okay with him/her being included in BOOST3 without giving your consent ahead of time.	57%	20%	16%	6%	0%	#	567
	326	114	93	34	0		
Do you think that BOOST3 researchers will seriously consider what community members like you have to say about this study before starting it?	73%	0%	15%	0%	12%	#	621
	452	1	95	0	73		
Do you feel that you have been given enough information to give your informed opinion about whether you think it is okay for researchers to do the BOOST3 study?	85%	0%	1%	0%	13%	#	557
	474	0	7	1	75		
Would you like to tell doctors that you do not want to participate in BOOST3?	12%	0%	0%	3%	85%	*	598
	74	2	0	15	507		

Summary of open ended comments.

# indicates comments coded as supportive
* indicates comments coded as concerned
+ indicates comments truncated at 430 characters

All Comments

Positive Comments about BOOST "Seems to be a good study and improved care of TBI is important"	#
Positive Comments about BOOST I believe there is benefit to knowledge gained from study	#
Positive Comments about BOOST "Sounds fascinating"	#
Positive Comments about BOOST "The doctors at Haborview saved my daughter's life. I am grateful and support this research."	#
Positive Comments about BOOST I know someone with a TBI, I support any research that can help.	#
Positive Comments about BOOST Research that helps TBI is important.	#
Positive Comments about BOOST Research that helps brain injury is important.	#
Positive Comments about BOOST This research sound like it is important to do. I support it.	#
Positive Comments about BOOST "This study is important."	#
Positive Comments about BOOST Research that helps TBI is important.	#
Positive Comments about BOOST This sounds good. I support it.	#
Positive Comments about BOOST I would want this done to me and my family.	#
Positive Comments about BOOST Research that helps TBI is important.	#
Positive Comments about BOOST I am in favor of this study. My child had a TBI.	#
Positive Comments about BOOST My husband fell and then had a stroke. He was in a stroke study. I am in favor of research. I understand why in emergencies you cannot always ask permission.	#
Positive Comments about BOOST Research that helps TBI is important.	#
Positive Comments about BOOST "Brain injury research is important."	#
Positive Comments about BOOST "It is important to improve TBI treatment."	#
Positive Comments about BOOST "My brother had a brain injury and he may have benefitted from information learned by this study."	#
Positive Comments about BOOST I support TBI research.	#

Positive Comments about BOOST I support TBI research.	#
Positive Comments about BOOST I believe there is benefit to knowledge gained from study	#
Positive Comments about BOOST I believe this study will help to decide if PbtO2 is needed.	#
Concern/worry about BOOST ICU RN: I am concerned that there may be confusion when blinding occurs. We are so used to treating the PbtO2 and now it may be unavailable.	*
Concern/worry about BOOST Study is important because of current practice managing TBI with both ICP and PbtO2. Do we need both?	*
Concern/worry about BOOST "I am worried that I may not receive the same care."	*
Concern/worry about BOOST "I don't want the doctors to experiment on me or my family."	*
Concern/worry about BOOST "I am afraid of research so I am not sure about this"	*
Concern/worry about BOOST It would be good to know if both values are important information.	*
Concern/worry about BOOST It would be good to know if both values are important information.	*
Other parents of participant: I support research that improves outcomes following TBI.	
Other TBI participant and family: We support this study and TBI research in general.	
Other Doctors at Harborview are very good. They do good work.	
Other "My son received excellent care following his TBI at Harborview and is doing well."	
Other I support research especially for TBI.	
Other "Doctors at Harborview are great."	
Other parents of participant: I support research that improves outcomes following TBI.	
Other parents of participant: I support research that improves outcomes following TBI.	
Other parents of participant: I support research that improves outcomes following TBI.	
Other parents of participant: I support research that improves outcomes following TBI.	
Other parents of participant: I support research that improves outcomes following TBI.	
Other TBI participant and family: We support this study and TBI research in general.	
Other TBI participant and family: We support this study and TBI research in general.	

Other parents of participant: I support research that improves outcomes following TBI.
Other parents of participant: I support research that improves outcomes following TBI.
Other parents of participant: I support research that improves outcomes following TBI.
Other parents of participant: I support research that improves outcomes following TBI.
Other "Staff at Harborview treated me even without insurance. I still go there for care."
Other "I had a brain injury and was in a coma for 6 weeks."
Other "I get all my care at Harborview, I trust the doctors will do the right thing."
Other "I don't trust doctors."
Other I support decisions of doctors at Harborview.
Other I support research especially for TBI.
Other I support research especially for TBI.
Other Visiting from another state and asked about other locations of the study. Referred to BOOST3 website.
Other Thank you for including me.
Information still needed about BOOST "Additional info concerning alternative treatments/options would be helpful."
Information still needed about BOOST "If the device monitors oxygen in a small area of the brain is that an adequate sample size?"
Information still needed about BOOST "If I understand correctly, the O2 monitor requires another hole in the skull-invasive and more info without known benefit."

Harborview Medical Center
Summary Report of Public Disclosures
The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN)

This is a report of findings from public disclosure events regarding a proposed clinical trial that can only be performed with exception from informed consent for emergency research. Public disclosure events were performed pursuant to 21 CFR 50.24 and related regulatory guidance documents.

The report consists of a two page overview, an additional page including a further description of the unique public disclosure (PD) events conducted and affiliated published source files.

Trial **Brain Oxygen Optimization in Severe Traumatic Brain Injury—Phase 3**

IND # U01 NS099046

The Clinical Coordinating Center has confirmed the following EFIC Plan criteria has been met:

1) At least 6 total events
2) At least 2 events from column A: National or local study website, Social media posting, Mailing (electronic or paper), Booth/Table event
3) At least 1 event from column B: Newspaper advertisement, Billboard/bus ad/pacard, Paid online advertisement
OR
4) At least 1 event from column C: Press release, News story, Radio/TV interview/PSA, Newsletter ad/article, Study material distribution

Report Date: Jul 19, 2019

This report includes findings from public disclosure (PD) events that took place between Apr 24, 2019 and Jun 17, 2019. It includes 11 events/activities reported by 1 BOOST3 site. These events involved reaching an estimated 232,545 community members locally through the PD process. Among the estimated community members reached, 0 individuals requested an opt-out mechanism.

Overview

No. of BOOST3 Sites reporting:	1
No. of activity reports:	11
No. of community members reached:	232,545
No. requesting an opt-out mechanism:	0
Types of community involved	
Percent geographic community:	55%
Percent condition-oriented community:	0%
Percent both Geo. & TBI-related	45%

Type of disclosure activities

C: Study material distribution	36%
A: Social media website/post	9%
B: Newspaper ad/article	27%
B: Paid online advertisement	0%
C: Locally ran news story or interview	0%
C: Newsletter ad/article	0%
A: Study/intitution website/post	9%
A: Booth/table event	18%
C: Press conference	0%
C: Radio/TV Interview/PSA	0%
A: Mailing	0%
B: Billboard/bus ad/placard	0%
Other	0%

Overview (continued)

Intended event audience		intended audience versus community type (number of events) geographic	condition-oriented
General public	36%	4	3
High-risk	27%	3	2
Medical professional	0%	0	0
Informal leader	0%	0	0
Ethnic/racial communities	18%	2	0
Formal leader	0%	0	0
Age specific groups	0%	0	0
Gender specific groups	0%	0	0
Parent	18%	2	0
Other	0%	0	0

totals events may be greater than 11 because some events included both community types

Detail on types of public disclosure activities

	no. of events	no. community reached*
C: Study material distribution	4	1,045
A: Social media website/post	1	237
B: Newspaper ad/article	3	230,500
B: Paid online advertistement	0	0
C: Locally ran news story or interview	0	0
C: Newsletter ad/article	0	0
A: Study/institution website/post	1	393
A: Booth/table event	2	370
C: Press conference	0	0
C: Radio/TV ad/PSA	0	0
A: Mailing	0	0
B: Billboard/bus ad/placard	0	0
Other	0	0

* Not all events within each type included an estimate number for community reached

Detailed View of Individual Events

Site	Date	Name of Event	Type of Disclosure	Estimated reached
Harborview Medical Center	4/24/2019	Study webpage on UW Medicine website	A: Study/institution website/post	393
Harborview Medical Center	5/21/2019	Interview with UW Medicine Newsroom	C: Newspaper ad/article	N/A
Harborview Medical Center	5/21/2019	Dr. Chesnut PI interview with UW Medicine Newsroom posted on YouTube	A: Social media website/post	237
Harborview Medical Center	6/8/2019	The Seattle Times newspaper ad	C: Newspaper ad/article	230,000
Harborview Medical Center	6/14/2019	Newspaper ad in La Raza	C: Newspaper ad/article	500
Harborview Medical Center	6/11/2019	Brochures in waiting area of Harborview Medical Center Clinics	C: Brochure/Poster/Flyer distribution	45
Harborview Medical Center	6/17/2019	Brochure in Patient/Family Resource Center at Harborview Medical Center	C: Brochure/Poster/Flyer distribution	250
Harborview Medical Center	5/11/2019	Seattle Bike Rodeo and Family Safety Fair	A: Booth/table event	250
Harborview Medical Center	5/19/2019	Touch a Truck Interactive Children's Event	A: Booth/table event	120
Harborview Medical Center	4/26/2019	Filipino Senior and Family Center	C: Brochure/Poster/Flyer distribution	350
Harborview Medical Center	5/1/2019	Lazarus Day Center Lunch	C: Brochure/Poster/Flyer distribution	400

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:

- Harborview Medical Center

Contact Us

BOOST3 Study
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Phone: 206-897-1779
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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.

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TECHNOLOGY

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TECHNOLOGY

Seattle, WA, Amazon Web Services, Inc. seeks candidates for the following (multiple positions available):

Professional Services II - Cloud Infrastructure Architect; Job Code: 20273.2335.2: SERVE AS A PRIMARY TECHNICAL CONTACT TO AWS CLIENTS AND/OR DEVELOPMENT PARTNERS TO OWN AND DRIVE PROJECTS AND ENGAGEMENTS INVOLVING THE ARCHITECTURE, DESIGN, DEVELOPMENT AND IMPLEMENTATION OF AMAZON'S UTILITY COMPUTING WEB SERVICES. LEAD AND COLLABORATE WITH CUSTOMER AND PARTNER TEAMS ON A VARIETY OF ENGAGEMENTS. REQUIRES UP TO 50% TRAVEL TO AMAZON OFFICES AND CLIENT SITES NATIONALLY. REMOTE WORK FROM ANYWHERE IN THE UNITED STATES PERMITTED.

Candidates must respond by mail referencing the specific job code to: Amazon, PO Box 81226, Seattle, WA 98108.

TECHNOLOGY

Seattle, WA, Amazon Web Services, Inc. seeks candidates for the following (multiple positions

IT/Software Development

TECHNOLOGY

Securitas Security Services has job openings in Redmond, WA:

SharePoint Developers [Req #9D01] Maintain & expand the capabilities of Microsoft Datacenter Physical Security Group's SharePoint Site;

SharePoint Site Administrator [Req #9F01] Serve as the 1st line support & troubleshooting technician for all issues related to the SharePoint Site.

Mail resume to K. Curtiss, HR MGR, Microsoft, RedWest E 2331, 5600 148th Ave. Ne, Redmond, WA 98052

User Experience Designer sought by Zillow, Inc. for Seattle, WA office. Responsible for leading the design of unique SW apps that impact how consumers interact w/ web & mobile platforms. Req: MS or foreign equiv in Info. Design, Visual Design, Engg, or rltd + 2 yrs exp as a User Experience Designer, or rltd, which includes 2 yrs exp in: leading the UX design process from conception to completion; developing SW solutions to improve efficiency & user experience; creating compelling user experiences through a user-centered design process, which includes researching, designing, & integration; & using web design & prototyping SW & tools w/ InVision. BS + 5 yrs progressive, post-bachelor exp OK. Reply to: Job # P18984, 1301 2nd Ave, Fl 31, Seattle, WA 98101 or jobs@zillow.com to apply.

Witekio Corporation seeks Embedded Software Engineer to work in Bellevue, WA. Prfrm driver & middlwre or applictn dvlpmnt on variety of embedded hardwre platfrms. Degree & commensurate exp. req'd. Send resume to jmorrow@witekio.com & refrnc ESE0519.

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(lululemon usa inc.; Seattle, WA): Lead the application team to support WMS issues across lululemon's distribution centers. Reqs: Must have a Bachelor's deg in Comp Sci, IT Mgmt, or rel field, + 5 yrs of progressive post-bac exp supp Manhattan assoc WMOS. Must have 5 yrs of exp writing complex SQL Stment for report and system issue trble shoot; 3 yrs of exp Unix/Linus operating systems and Cognos and/or Jasper; 2 yrs of prog resp exp lead information tech team. Apply by mail to: ATTN: SASC, lululemon usa inc., 1191 Second Avenue, Suite 900, Seattle, WA, 9810

Management/Executive

Management

Amazon.com Services Inc. seeks candidates for the following (multiple positions available) in Seattle, WA:

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Marine/Fishing

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Upholsterer (Seattle, WA): Make, restore, repair, or create custom upholstered furniture using hand tools, power tools, sewing machines, instruments, and knowledge of fabrics and upholstery methods. See full job description at https://qagroup.us/careers/

Requirements: High School Diploma/GED; 3 years' experience in furniture upholstery.

Submit resume & required experience & education details by 6-29-19, to Kevin Truan, QA Group, kevin@qagroup.us.

Sales - Company Employed

Amazon.com Services, Inc. - Seattle, WA. Senior Product Manager - Technical. Gather, research & define product & bus. reqs., write detailed functional specifications, & coordinate efforts to scope, schedule & deploy new feature sets, innovations & opportunities based on specific market segments & targeted customers. Multiple job openings.Send resume, referencing AMZ3209 to: Amazon.com, P.O. Box 81226,Seattle, WA 98108. EOE.

Transportation/Warehouse

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SEVERE BRAIN TRAUMA STUDY
Harborview Medical Center is conducting a research study to learn if either of two strategies for monitoring and treating patients with severe traumatic brain injury in the intensive care unit (ICU) is more likely to help them get better. Because head injury is a life-threatening condition requiring immediate treatment, some patients will be enrolled without consent if a family member or representative is not rapidly available. Before the study starts, we will consult with the community. We welcome your feedback and questions. For more information or to decline participation in this study, please visit **boost3trial.org or contact our study staff at boost3@uw.edu**
Primary Investigator: Dr. Randall Chesnut, MD
Study Coordinator: Pat Klotz, RN

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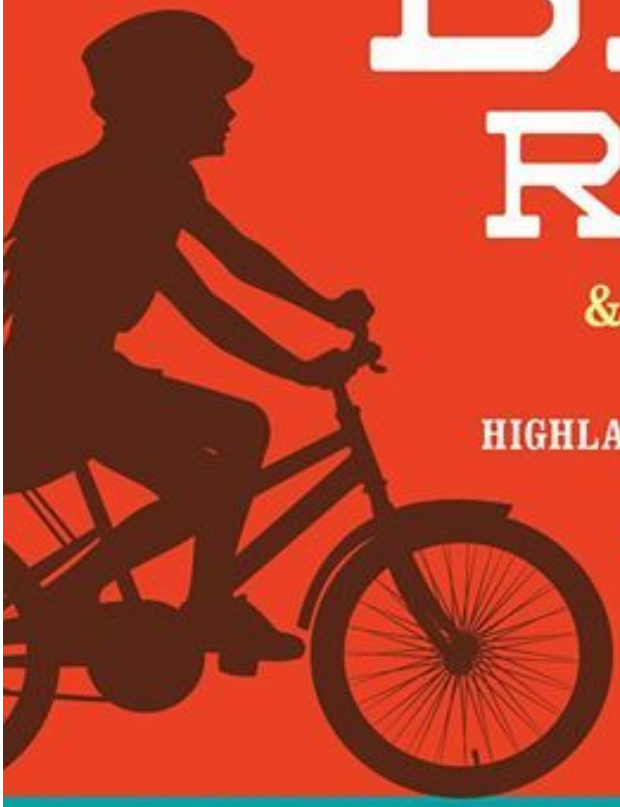

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SATURDAY, 10AM–12PM

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There will be free helmets and other prize giveaways. **Course #437**

Bike Rodeo & Family Safety Fair

In partnership with Safe Kids Seattle South king County and collaboration with other emergency services, the City of Renton is offering a FREE bike safety event.

Bring your own bike and try out your skills in our bike obstacle course and road safety test. Get helpful bike maintenance tips from our experts! Families will also receive valuable safety information and helpful tips from many agencies.

There will also be helmets and other prize giveaways!

Register at http://bit.ly/2GXkypz.

Things To Do | All Events | Community & Civics | Family

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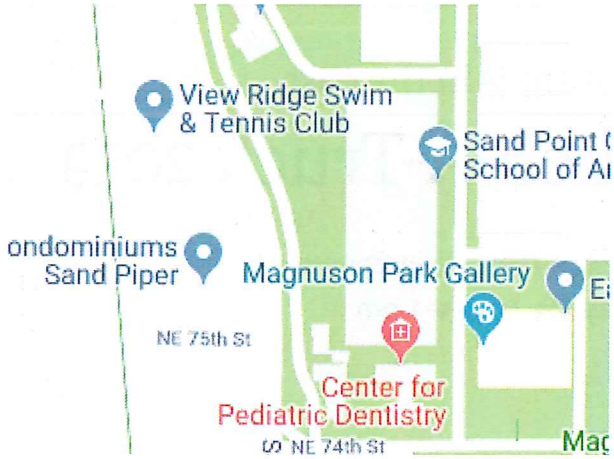

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EVENT TIMES

This event is in the past.

Sun May 19, 10 am–1 pm

CATEGORY

Family, Community

BOOST3: Brain Oxygen Optimization in Severe Traumatic Brain Injury, Phase 3

Overview

Researchers at the University of Washington based at Harborview Medical Center are joining a national study through the Strategies to Innovate Emergency Care Clinical Trials Network (SIREN), to learn if either of two strategies for monitoring and treating patients with traumatic brain injury (TBI) in the intensive care unit (ICU) is more likely to help them get better.

Randall Chesnut, MD is principal investigator for this clinical study.

Traumatic brain injury (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.

Both of the strategies in this study 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.

The researchers are seeking feedback from the community regarding the conduct of this study. There is additional information in the attached power-point presentation. There is

also a short survey attached where you can add your feedback. Additionally, individuals can opt out of participating in the study by wearing a bracelet that reads "NO STUDY." The bracelet indicates that, should you be injured, medical care providers will exclude you from the research. If you have questions or would like additional information about this study please contact the Research Team at 206.897.1779 or email: boost3@uw.edu.

We will attempt to return e-mails and calls during business hours. We will not keep any personal information you provide, nor will we share any of your personal information with anyone.

Seattle enrollment begins this summer, and the study will conclude in early 2023.

BOOST3 Resources

BOOST3 Community Consultation

Opt-out bracelet form

Online survey

Self-administered survey

YouTube: Emergency care of victims of brain trauma

National Institutes of Health Clinical Trial

May 21, 2019

Studying how to monitor and treat TBI

DOWNLOAD ASSET PAGE:

Download soundbites of Dr. Randall Chesnut.

Every 15 seconds, someone in the United States sustains a traumatic brain injury resulting from external forces such as a car crash or a fall. Every five minutes, a person is disabled as a result.

Dr. Randall Chesnut, a neurosurgeon at Harborview Medical Center, is UW Medicine's lead investigator in a national study of two standard-care approaches to monitoring and treating TBI. In one approach, care is focused on preventing high intracranial pressure caused by a swollen brain. The other approach aims to prevent both intracranial pressure and low brain oxygen levels. The study intends to generate data-based evidence about whether one approach is safer and more effective.

For details, or to opt out of the study, visit the BOOST3 study.

Category: Research

Tags: TBI research study neurology

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Randall Chesnut, M.D.
Professor, Neurological Surgery, Orthopedics and Sports Medicine
Neurosurgeon, Harborview Medical Center

31-57 there are several ways of treating brain injury based on monitoring. The established way is based on monitoring the pressure in the head. We think that we have a monitor that allows us to improve care by looking at brain oxygen, but we're not sure if the way it works and the way we're using it actually does improve care. We think it might but we need to know before we put it into general practice

731-747 we've been doing this for years to measure pressure and it's safe and effective. This is no more holes, no real more pokes, it's just instead of putting in one monitor, we put another one in next to it.

340-402 this is the first attempt at that that can be used in general and we need to know if it works because it may allow us to categorize patients into certain subgroups that require different treatments. It may allow us to avoid overtreatment and undertreatment, so if it works it could make a big interest in head injury, big difference

200-218 This is an emergency study. It's done on comatose patients and we need to start our treatments very early, which means we can't do the traditional discussing the case and the study with the patient and having them write a consent.

630-654 being in this study is not going the change the very aggressive traumatic brain injury care you get here. Either arm, you're going to be very carefully observed, treated aggressively, and all the technology and knowledge that we have is going to be applied to making you better. The only difference will be the subtleties that are related to this study.

953-1007 if people decide that they would not want to be in such a study, they can visit our website and there are several ways of opting out so if you come in we will not consider you a candidate for the study

913-939 the brain can improve a lot. It can recover. But if something that it doesn't like happens afterwards, or it swells too much, etc., then it won't recover, so mostly what our job is in the year 2019 is optimizing the healing environment for the brain and that's what we're trying to do with these monitors.

For more information about the BOOST3 study: https://www.uwmedicine.org/research/research-studies/boost3

CLASIFICADOS

Nuevo Teléfono 425-339-3042

Empleo / General

ESTAMOS CONTRATANDO

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- Procesamiento de Carne

Instalación ubicada en Kent, WA.
Por favor llame a Kevin al 253-377-0950

Empleo / General

Kitsap Transit
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206-330-3999

Empleo / General

Se llevará a cabo en esta área un estudio de atención de emergencia para víctimas de traumatismo cerebral grave.

Harborview Medical Center
llevará a cabo un estudio de investigación que busca saber si alguna de las dos estrategias para controlar y tratar a los pacientes con traumatismo craneoencefálico en la unidad de cuidados intensivos (ICU, por sus siglas en inglés) tiene más probabilidades de ayudarlos a recuperarse. Dado que las lesiones en la cabeza son potencialmente mortales y requieren tratamiento inmediato, algunos pacientes serán inscritos en el estudio sin que se obtenga el consentimiento previo si un familiar o un representante no están disponibles de inmediato. Antes de que el estudio comience, consultaremos a los miembros de la comunidad. Nos gustaría recibir sus comentarios y preguntas. Para obtener más información o para rechazar la participación en este estudio, visite el sitio web boost3trial.org o comuníquese con el personal del estudio llamando al:
boost3@.uw.edu
Investigador principal: Dr. Randall Chesnut, MD
Coordinador del estudio: Pat Klotz, RN

BOOST-3

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NO ESPERES DEMASIADO LARGO O ¡TODAS LAS RUTAS SE ACABARÁN!

Trial	**Brain Oxygen Optimization in Severe Traumatic Brain Injury—Phase 3**		
IND #	**U01 NS099046**	ClinicalTrials.gov ID	**NCT03754114**

This report consists of a one page response to local context questions that the site study team was asked to answer, and any additional infomation the site wanted to share.

Local Context responses

1. Please provide the demographics of the catchment area in which BOOST3 subjects could be drawn:

Harborview Medical Center is the only Level 1 Trauma Center serving population of Washington, Alaska, Montana and Idaho. Because of the time from injury to randomization criteria the focus of the local context is King County, WA where Harborview is located. Population of King County is 2.19 million. Male 49.8% Female 50.2% Age: 82% are age 15 and older. Race: White 69% . Black/African 6% . Native American 0.8% . Asian 15% . Pacific Islander 0.8%. Ethnicity: Hispanic/Latino: 8%

2. Please provide any additional or unique variables related to patients seen at your site that could be potential BOOST3 subjects: (e.g., high percentage of homelessness, a large reservation population, specific religion or language cohorts, etc.):

Jan 2019 homeless count was 12,000 in King County. This includes those living in shelters, in vehicles, in tent city encampments and on the streets.

3. Please provide information regarding any unique factors about your local institution/culture in which the research will be conducted(e.g., laws, practice patterns, etc.):

Harborview Medical Center has been participating in EFIC studies for the past 20 years. Consultation with the community has always been positive and indicate appreciation for a chance to be heard.

4. Please provide what resources your institution has to help study teams reach the community in which the research will be conducted: (Example: A Special Community Advisory Board):

University of Washington Strategic Marketing and Communication department assists with identifying community group contacts and coordinates web site development and social media notifications.

5. Please describe how you met the goals of the EFIC plan/community consultation process and if there were any recommendations from the community for changes to the conduct of the study necessary to address specific site characteristics.

The CC/PD activities performed met the goals set in the BOOST EFIC plan. Specifically, the activities showed respect for persons by: seeking and engaging in meaningful dialog about the study. talking to people in their environment reaching out to people during community life

We ensured that the activities provided a means for affected communities to provide input by: meeting with people of all ages (college to seniors), backgrounds (socio-economic), race, ethnicity and medical risk and experience. meeting with patient groups, clinical groups.

We attended events that are attended by a diverse cross section of the community like the bike safety fair, the various senior groups and the Farmer's Market.

We showed respect for communities by engaging with representatives from local civic organizations.

We showed respect for individuals who have, or may be at greater risk for TBI by presenting study to mountain climbers, athletes, brain alliance association and seniors. We also left flyers in locations visited by this population (head injury clinic and support group).

The take away messages from our CC/PD: the population generally favors EFIC research and the majority of those learning about the study would be willing to participate if they suffered a TBI. The concerns we heard were relatively infrequent and mostly involved transparency.

EFIC Packet – Harborview Medical Center

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