

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 1, 2019

This report includes findings from community consultation events that took place between Mar 30, 2019 and May 16, 2019. It includes findings from 11 events/activities reported by 1 BOOST3 site. These events involved 171 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, 73% involved a geographic community, 18% a condition-oriented community, and 9% involved both. Of all participants 154 provided feedback including 922 answers to closed ended questions and 75 open ended comments. Among responses expressing an opinion 91% of closed ended and 89% of open ended comments were supportive.

Overview

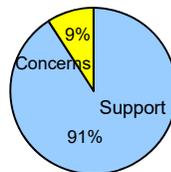
Number of Hubs reporting:	1
No. of activity reports:	11
No. of participants:	171
Types of community involved	
Percent geographic community:	73%
Percent condition-oriented community:	18%
Percent both types of community:	9%
Type of consultation activities	
A: Presentation w/ an Existing Group	45%
B: In-person Survey/Interview	9%
A: PI staffed Booth Event	0%
A: Focus Group	0%
A: Convened Meeting w/ RSVP	9%
B: Non-PI staffed Event	27%
B: Electronic Survey (not social media)	0%
B: Telephone Survey	0%
B: Social media Event	9%

Participant Demographics

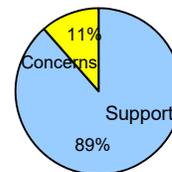
Age (average)	52 years
Female	
Male	34%
	66%
Race	
White	68%
Black/African American	9%
Asian	9%
Other race	7%
American Indian or Alaska Native	2%
Native Hawaiian or Pacific Islander	3%
More than one race	2%
Ethnicity	
Hispanic/latino	13%
Non-hispanic	87%

Feedback Summary

# of individual survey respondents	154
Total # of closed ended responses	922
Total # of open ended comments	75



Closed Ended Responses
Expressing Opinion
n= 835



Open Ended Comments
Expressing Opinion
n= 35

Overview (continued)

Intended event audience		intended audience versus community type (number of events)	
		geographic	condition-oriented
General/geographical community	73%	7	1
Healthcare professional	9%	1	0
High risk specific	9%	1	0
Informal leader	0%	0	0
Formal leader	0%	0	0
Ethnic/racial community	0%	0	0
Age specific	0%	0	0
Parent	0%	0	0
Other	9%	0	1

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

Detail on types of community consultation activities

	<u>no. of events</u>	<u>no. of participants</u>
A: Presentation w/ an Existing Group	5	100
B: In-person Survey/Interview	1	20
A: PI staffed Booth Event	0	0
A: Focus Group	0	0
A: Convened Meeting w/ RSVP	1	6
B: Non-PI staffed Event	3	41
B: Electronic Survey (not social media)	0	0
B: Telephone Survey	0	0
B: Social media Event	1	4

Detailed View of Individual Events

Site	Date	Name of Event	Type of Consultation	Number of Participants	Participant Average Age
SF General Hospital	04/25/19	San Francisco Motorcycle Club monthly meeting	A: Presentation w/ an Existing Group	30	53.0
SF General Hospital	04/08/19	Brainstorm - TBI support program meeting	A: Presentation w/ an Existing Group	15	52.0
SF General Hospital	04/30/19	San Francisco Police Department Captain's meeting	A: Presentation w/ an Existing Group	35	50.0
SF General Hospital	05/16/19	Swords to Plowshares Veteran's Housing Monthly Meeting	A: Presentation w/ an Existing Group	14	60.0
SF General Hospital	03/30/19	South End Rowing Club/Dolphin Club	A: Convened Meeting w/ RSVP	6	47.0
SF General Hospital	05/10/19	San Francisco Fire Department Paramedics at Base Station	B: In-person Survey/Interview	20	37.0
SF General Hospital	03/31/19	Sunday Streets Excelsior Neighborhood Event	B: Non-PI staffed Event	10	54.0
SF General Hospital	04/14/19	Sunday Streets Tenderloin. Neighborhood open to pedestrians/bicyclists	B: Non-PI staffed Event	17	43.0
SF General Hospital	05/05/19	Sunday Streets Bayview/Dog Patch Neighborhood Event	B: Non-PI staffed Event	14	0.0
SF General Hospital	05/06/19	Barbara Roach & Katie Burke Pizza Night	A: Presentation w/ an Existing Group	6	59.0
SF General Hospital	05/08/19	Brain and Spinal Injury Center UCSF Facebook Page Responses	B: Social media Event	4	60.0

Goals of the EFIC Plan

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

Our activities showed respect for persons by seeking and engaging in meaningful dialog in groups as well as one on one interactions, by talking with people on their own turf when invited, by offering to do presentations if requested by the organizations we provided brochures to and by talking about research at other events.

We also placed ads in San Francisco English, Spanish, Chinese and LGBTQ newspapers.

We ensured that the activities provided a means for affected communities to provide input by meeting with people of diverse ages, backgrounds, race, ethnicity, medical risk and experience. We were particularly cognizant, respectful and inclusive of the economic extremes in San Francisco. We met with TBI survivors, the SF Motorcycle Club, SF paramedics, public community groups and formerly homeless veterans in order to accomplish this. The age range on our surveys was 24-78 years of age.

We showed respect for individuals who have, or may be at greater risk for TBI by talking to motorcycle clubs and TBI support groups. The study team also reviewed stats regarding age in prior TBI studies which showed the majority of TBI patients are over 50 years of age. Our CC/PD activities reflect this age demographic.

Take away messages from our CC/PD gleaned from the quantitative and qualitative data detailed in this report are that there is widespread support for this BOOST3 and EFIC research. A majority of those learning about this research would be willing to participate if they suffered a TBI.

Subjective take away knowledge is that EFIC research is a challenging concept for the public to comprehend. As basic an explanation as possible should be given at the outset with as much time as possible given to answering questions.

The concerns we heard were relatively infrequent and mostly involved any type of research without consent if the person is/were a parent whose child had a brain injury. No recommendations for changes to study conduct were received from the community.

Event Narrative Summary

Name of Event	Type of Consultation
<p>San Francisco Motorcycle Club monthly meeting</p> <p>The study presentation was done at the club's weekly Thursday night meeting. The PI, primary study coordinator and IRB analyst were present. There were approximately 32 members present with 30 filling out surveys. One of the club board members was an RN who used to work at SFGH and one member is a current SFGH ICU RN. They were able to also provide information to club members during the discussion. During the PI's talk, everyone was quiet and paid attention. Initial questions were geared toward clarifying what EFIC exactly is and that we weren't there to enroll people ahead of time in case they had a TBI. Some people had questions about the actual protocol, seemed understanding of EFIC and unconcerned about the possibility of being enrolled without consent. People mentioned their own TBIs. There were no concerns expressed about study procedure and the group was generally excited to hear about research done at SFGH. The meeting ended with members taking a vote that the club buy the study team a drink after the meeting. The study team remained after, talking to individual members. One member commented to the study coordinator that it must be difficult to talk with people's families about research when such a tragic event has taken place. The IRB analyst present asked members if they understood that the research could be done without consent and they all said yes. They expressed to her their respect and admiration to the folks at SFGH and their support for research. The group thanked the study team for speaking with them and appreciated the opportunity to participate."</p>	<p>A: Presentation w/ an Existing Group</p>
<p>Brainstorm - TBI support program meeting</p> <p>Brainstorm is a day program serving adults with TBI and/or acquired brain injury. At this event, the clients were present with their individual caretakers as well as staff and the program manager. There were 3 IRB analysts present with the study coordinator and research manager. One participant told the study team his story of being a construction worker over 15 years ago and accidentally having a nail go into his skull/brain from a nail gun. He remembered his MD's name in the ICU at SFGH and it was the BOOST3 PI. One client who was gravely disabled, wheelchair bound wearing a helmet due to intractable seizures, with severe drooling and slurred speech, interrupted the presenting study coordinator to ask "What is the main goal of the study?" His speech was so slurred that his caretaker had to tell the study team what he said. The program manager had many questions for the study team after including why we couldn't use existing data to come to this conclusion, and more about current practices with Pbt02 monitoring. He thought it was obviously better to maintain the oxygen level in the brain than not. He had a much better understanding and curiosity than the clients or other staff and engaged with study staff for a while. The caretakers assisted the clients with filling out surveys and filled them out themselves also along with the program staff. The staff was supportive of the research but also appeared distracted as other clients came in and out of the area and the current clients had to go on to their next activity.</p>	<p>A: Presentation w/ an Existing Group</p>
<p>San Francisco Police Department Captain's meeting</p> <p>This is the monthly SFPD Mission Station Community meeting. Members of the community can come with questions/concerns or to listen. The station captain runs the meeting with other police officers present who give an update on crime/issues in the area. SFGH is in this area. There are usually 1-2 community presenters also. The PI, study coordinator, research manager and IRB analyst were present. The station captain was very friendly prior to the start of the meeting and asked questions about BOOST3. One community member asked us who we were and then told the study team about his TBI. There was much conversation prior to the start of the meeting among people who arrived early and many attendees asked the study team who we were and what we were going to talk about. The presentation was well received and attentively listened to. Some police officers filled out surveys after the presentation. There were more written responses than verbal ones. Attendees were encouraged to take brochures if they wanted further information, if they had questions or wanted to opt out. The attendees were a wide variety of community members."</p>	<p>A: Presentation w/ an Existing Group</p>
<p>Swords to Plowshares Veteran's Housing Monthly Meeting</p> <p>This is a monthly meeting of formerly homeless veterans housed by the Swords to Plowshares non-profit org that provides case management, employment training, housing and legal assistance to veterans in SF. Veterans and staff were present. The study coordinator and research manager were present. Prior to the study presentation, 2 outreach workers who were recently discharged veterans, spoke briefly with the vets. They were ready to leave and the study coordinator asked them if they could stay for the presentation so we could get their feedback also. They were happy to participate and this led to a discussion after about BOOST3, the increase in TBI in the military due to IEDs, available TBI resources in SF and an exchange of contact information. One told the study team about his TBI from an IED while on active duty. As usual, the EFIC concept was difficult for people to understand. A common misconception is that we are enrolling people ahead of time and if they have a brain injury, they will be enrolled. One female veteran wanted to clarify that the clinicians wouldn't be able to know the Pbt02 in the ICP only group surprising the study staff with her level of understanding. The level of interaction with the study team increased after the presentation when people approached the study team with their TBI and/or SFGH experiences. The overall feeling was of support for any TBI research.</p>	<p>A: Presentation w/ an Existing Group</p>

Name of Event	Type of Consultation
<p>South End Rowing Club/Dolphin Club</p> <p>The South End Rowing Club is an athletic club founded in the late 19th century. It's composed of highly engaged SF residents from MDs to local politicians, RNs, librarians and others. An email was sent out with 4 responders. One person had a severe TBI and he expressed excitement about attending. His wife and close friend were going to come also, all SF residents. Another woman said her mother died when she was a child from a massive stroke and was very interested in any research in the area of neurology. This was a brief presentation with a small group that came because they were already excited to hear about BOOST3. The high point of this event was the TBI survivor telling his story. He had been the victim of an assault and went by ambulance to SFGH for his injury. He spent a week in the ICU and has no memory of the assault. He made an almost complete recovery. This was the main area of discussion for the group. This group was very intelligent and understood the EFIC concept and the basic study procedure. There weren't a lot of questions.</p>	<p>A: Convened Meeting w/ RSVP</p>
<p>San Francisco Fire Department Paramedics at Base Station</p> <p>The study coordinator went to the SF Fire Department central paramedic station where paramedics and EMTs who were starting or ending their shifts filled out self administered surveys. The captain working at the station told the crews that before they start their shift or go home, they needed to fill out a survey. Many were excited and interested. Some were in a rush but participated. One medic yelled to his partner, "hey, you have to fill out a survey. It's about helping TBI patients at the General". One medic told the coordinator he was in a TBI study with the VA after suffering a TBI during active duty while in the military. The station was crowded and bustling with activity as people came and went tending to their other duties so there were not a lot of questions. A few medics asked if they needed to do anything in the field for the study. The captain brought up the idea of a possible "research paramedic" position being created to keep a connection between the paramedics and research staff so pre hospital providers could stay informed on current research at SFGH. Some of the paramedics participated in the RAMPART study or had heard about it so were familiar with EFIC research</p>	<p>B: In-person Survey/Interview</p>
<p>Sunday Streets Excelsior Neighborhood Event</p> <p>This is a bustling working class neighborhood with a large Latino and Asian presence. As with other Sunday Streets events, it's densely populated with a variety of other social service, public health, advocacy and other groups doing community outreach. The groups that are in the same general vicinity get to know one another during the course of the day, converse, ask questions, etc. and this becomes a secondary way of disseminating study information aside from surveys. At this event, the study coordinator was excitedly approached by a TBI survivor who was thrilled to see our table. She filled out a survey and invited the coordinator to their Pizza Night to talk about BOOST3 and meet the other group members. One IRB analyst attended for an hour.</p>	<p>B: Non-PI staffed Event</p>
<p>Sunday Streets Tenderloin. Neighborhood open to pedestrians/bicyclists</p> <p>The Tenderloin is a bustling combination of a lower income immigrant and single room occupancy skid row neighborhood that is densely populated with many social services and small immigrant owned businesses. This event was an engaging and stimulating exchange of ideas and information between the study team, the other organizations that had tables there, along with the residents of the area. Among other engaging exchanges, the research manager who was present had an extended conversation with 2 workers from Glide(a large social service/activist/spiritual organization) about BOOST, research and SFGH. They were glad our outreach was being done in the Tenderloin and had praise for SFGH being a safe haven in SF. They talked about the stigma of being experimented on but that the study team was doing a great job of putting a human face to the research. A woman from an organization that provides extra traffic crossing guards for local schoolchildren was thrilled to participate. Her primary language was Arabic but she clearly understood the EFIC and study concepts</p>	<p>B: Non-PI staffed Event</p>
<p>Sunday Streets Bayview/Dog Patch Neighborhood Event</p> <p>At this event, our location was out of the main stream of pedestrians so many surveys were filled out by other presenters including a few physical therapists who manned a table nearby. They were interested as they worked with TBI patients. The study coordinator met 2 employees from a pedestrian and bicycle safety advocacy group that she had previously spoken and emailed with in regards to sending out a tweet about BOOST3. Though both group's communication teams eventually declined to tweet a message about BOOST3, the SF bicycle Coalition and WalkSF group employees became very familiar with BOOST3. Two employees of WalkSF also filled out surveys.</p>	<p>B: Non-PI staffed Event</p>

Name of Event	Type of Consultation
<p>Barbara Roach & Katie Burke Pizza Night</p>	<p>A: Presentation w/ an Existing Group</p>
<p>Though a small group and not on our EFIC plan initially, the study coordinator accepted the invitation from one of the group members she met at Sunday Streets Excelsior. These are long term TBI survivors who have been meeting monthly for 20+ years. One person had filled out a survey previously, one older man said he had too much brain damage to understand and one woman became anxious in regards to the survey so didn't fill it out. The group was very friendly and obviously happy to have a member of the TBI research community at their dinner. A local IRB analyst was also present. They told their injury stories along with their hospitalizations, recoveries and current challenges. One male spoke about a new motor recovery study he just enrolled in. They seemed to want the coordinator to listen to their stories rather than hear about BOOST3 and all appeared cognitively challenged. The group is very familiar with all the TBI groups in SF, the group leaders and history. Though this group contributed only 3 surveys, it was obvious that having the study coordinator there provided a lot to the group. The point of this event became evident early in the meeting. It wasn't that study staff get them to understand EFIC/BOOST3. The point was that they were happy we were there and that they had people from the research community hearing their devastating stories. The group was completely supportive of TBI research. For the study coordinator and the IRB analyst, hearing about rural care for TBI 30 years ago reinforced the need for this research. The group member who invited the study team called the next day to say how much it meant to them that we attended. It was agreed that we would let them know when BOOST3 started and maintain a connection with the TBI Pizza Night group. An open invitation was extended to the coordinator and analyst to join them any time.</p>	
<p>Brain and Spinal Injury Center UCSF Facebook Page Responses</p>	<p>B: Social media Event</p>
<p>This is the Facebook page of the UCSF Brain and Spinal Injury Center (BASIC) at SFGH. BASIC engages in high level basic science, translational and clinical research to achieve a better understanding of treatments for TBI and SCI. An article about BOOST3 was posted on the site with a link to the online survey</p>	

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	Yes or Strongly Agree	Agree	Neutral	Disagree	No or Strongly Disagree	Number of Respondents
BOOST3 is an important study to do.	67% 103	26% 40	6% 10	0% 0	1% 1	# 154
If you had a traumatic brain injury, you would be okay with being included in BOOST3 without first giving your consent ahead of time.	55% 86	27% 42	11% 17	3% 4	4% 6	# 155
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.	47% 72	27% 41	14% 22	6% 9	6% 10	# 154
Do you think that BOOST3 researchers will seriously consider what community members like you have to say about this study before starting it?	71% 113	0% 0	24% 38	0% 0	5% 8	# 159
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% 129	0% 0	0% 0	0% 0	15% 22	# 151
Would you like to tell doctors that you do not want to participate in BOOST3?	11% 16	0% 0	0% 0	0% 0	89% 133	* 149

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 Thank you for your RESEARCH!	#
Positive Comments about BOOST very informative information -	#
Positive Comments about BOOST I feel the program as laid out is fair & ethical	#
Positive Comments about BOOST It's good job keep it up	#
Positive Comments about BOOST Thank you!	#
Positive Comments about BOOST Please keep the San Francisco Medics updated and in "the loop". Thank you	#
Positive Comments about BOOST Any research study for the overall benefit of patient care is one step closer to a quality of living.	#
Positive Comments about BOOST I think this would be an important study to potentially relieve the effect of a TBI, aneurysm or stroke.	#
Positive Comments about BOOST The more we learn about the brain, the better for all!	#
Positive Comments about BOOST Good idea Do it!	#
Positive Comments about BOOST Good luck w/ the study	#
Positive Comments about BOOST I am an organ donor and this is noted on my license. In my opinion, I am donating my body to science and would also do this in the the case of this study. This should be an opt in next to organ donation as well as other similar studies.	#
Positive Comments about BOOST Please Do This	#
Positive Comments about BOOST More Info = Better for Patient	#
Positive Comments about BOOST This is very worthwhile research so I hope it continues.	#
Positive Comments about BOOST Thank you for reaching and helping.	#
Positive Comments about BOOST More info will be better.	#
Positive Comments about BOOST I THINK THIS IS A GREAT STUDY TO HAVE IN MY OPINION	#
Positive Comments about BOOST Thank You for your Service	#
Positive Comments about BOOST Thanks for doing this!	#

Positive Comments about BOOST Just keep the good work _	#
Positive Comments about BOOST This information is important, I support research in ED medicine.	#
Positive Comments about BOOST Great & helpful study for health of people	#
Positive Comments about BOOST This sounds like a much needed topic for study. I am surprised this has not been extensively researched previously! Go FOR IT!!	#
Positive Comments about BOOST A study such as this would be a help for the patient in he himself measuring his progress.	#
Positive Comments about BOOST Excited to see this research being done!	#
Positive Comments about BOOST Constant improvement in treatment plans is essential, which can be achieved by research such as this.	#
Positive Comments about BOOST I think it's a good idea. Any help one can give to TBI is better than what is given now	#
Positive Comments about BOOST I have a remote TBI history and I want to thank you!	#
Positive Comments about BOOST I'm glad you're doing this important study.	#
Concern/worry about BOOST I would simplify the language conveying the treatment options to make sure all people understand what they're going into.	*
Concern/worry about BOOST Let people really know the five reasons behind it. A.I.	*
Concern/worry about BOOST Why would it not be feasible to use controls from hospitals that are not offering the experimental treatment. Potential for benefit is removed.	*
Concern/worry about BOOST want to know more about outcomes and effectiveness of those who have received either of treatment protocol	*
Other I think that this is an urgent need for knowledge about organization	
Other Unsure at this time. Having experienced TBI I need time to consider and answer.	
Other Depending on the level of care that is rendered in different stages of patient care.	
Other ADD TO ADVANCED HEALTHCARE DIRECTIVE	
Other You kind of need a college degree to understand this survey	
Other Thank you for including me in your survey	
Other Thank you for including me in your survey. The lecture was very interesting.	
Other Had a skull fracture at about age 7. Fell off the slide at school. About 12-14 feet head first to play ground.	
Other I think in this case, the proposed additional monitoring does not really require consent, but I would be leery of this in general, naturally. I am aware that sometimes overzealous intervention can impede outcomes.	

Other My head injury happened in 1978 as a result of an auto accident
Information still needed about BOOST A little more information on possible changes to oxygen level; given the randomization.
Information still needed about BOOST I was curious about the device itself
Information still needed about BOOST It's not simple enough to grasp what is the results or costs to the disadvantage populace.
Information still needed about BOOST As long as its a study-
Information still needed about BOOST Just reading this for first time so a longer personal consideration can be done.
Information still needed about BOOST I'd like to see more widespread information regarding this.
Information still needed about BOOST What treatment exactly will be performed on each of 2 groups and whether it is the same or not.
Information still needed about BOOST I'm not sure
Information still needed about BOOST More Research = Better Informed
Information still needed about BOOST Potential Side Effects
Information still needed about BOOST will some patients get no treatment at all?
Information still needed about BOOST What are possible (alleged) draw backs
Information still needed about BOOST Ongoing review will be shared w/ public how + when?
Information still needed about BOOST would like to learn more about mini strokes. Strokes is the brain. My brother was also in a coma and brain damages.
Information still needed about BOOST Pros + Cons
Information still needed about BOOST DETAILS ABOUT THE PROCEDURES
Information still needed about BOOST I'd like to know the number of patients who succumbed due to this procedure. I'd also like to know the number of patients who survived because of BOOST or survival rate.
Information still needed about BOOST What are the risks?
Information still needed about BOOST more info is always a good thing
Information still needed about BOOST I want to learn more. Need more information.
Information still needed about BOOST current results of ICP alone
Information still needed about BOOST If this were treatment guaranteed (or at least w/high probability of supporting my health) I would consider. Since its a study, that really concerns me.

Information still needed about BOOST Reading information to consider.
Information still needed about BOOST I need to digest what has been said and I need to know the effectiveness of study protocol
Information still needed about BOOST Risk factors or risks of further injury from study if none then no I have no problem with the study.
Information still needed about BOOST Does this study potentially impose additional risk to patient. If it is purely data gathering then I don't see any problem with it.
Information still needed about BOOST Would like to know When/where the results will be published
Information still needed about BOOST Have there been any prior studies or knowledge of which of the two monitoring strategies is better?
Information still needed about BOOST I WOULD LIKE ADDITIONAL INFO ABOUT THE FUTURE STUDY.
Information still needed about BOOST Please return with more information
Information still needed about BOOST Any information available. If I die due to this study, What benefits would I/my family receive

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 ClinicalTrials.gov ID **NCT03754114**

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/placard, Paid online advertisement
- 4) At least 1 event from column C: Press release, News story, Radio/TV interview/PSA, Newsletter ad/article, Study material distribution

Report Date: Jun 4, 2019

This report includes findings from public disclosure (PD) events that took place between Mar 31, 2019 and May 23, 2019. It includes 26 events/activities reported by 1 BOOST3 site. These events involved reaching an estimated 293,868 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:	26
No. of community members reached:	293,868
No. requesting an opt-out mechanism	0

Types of community involved

Percent geographic community:	92%
Percent condition-oriented commun	0%
Percent both Geo. & TBI-related	8%

Type of disclosure activities

C: Study material distribution	73%
A: Social media website/post	8%
B: Newspaper ad/article	15%
B: Paid online advertisement	0%
C: Locally ran news story or interview	0%
C: Newsletter ad/article	0%
A: Study/initiution website/post	4%
A: Booth/table event	0%
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	54%	14	2
High-risk	4%	1	0
Medical professional	0%	0	0
Informal leader	0%	0	0
Ethnic/racial communities	27%	7	0
Formal leader	0%	0	0
Age specific groups	12%	3	0
Gender specific groups	0%	0	0
Parent	0%	0	0
Other	4%	1	0

totals events may be greater than 26 because some events included both community types

Detail on types of public disclosure activities

	<u>no. of events</u>	<u>no. community reached*</u>
C: Study material distribution	19	668
A: Social media website/post	2	200
B: Newspaper ad/article	4	292,000
B: Paid online advertisement	0	0
C: Locally ran news story or interview	0	0
C: Newsletter ad/article	0	0
A: Study/institution website/post	1	1,000
A: Booth/table event	0	0
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
SF General Hospital	4/14/2019	San Francisco Examiner Newspaper	B: Newspaper ad/article	255,000
SF General Hospital	4/11/2019	El Tecolote Newspaper	B: Newspaper ad/article	10,000
SF General Hospital	4/28/2019	Sing Tao Daily Newspaper	B: Newspaper ad/article	10,000
SF General Hospital	5/8/2019	University of California San Francisco Brain and Spinal Injury Center Website	A: Study/institution website/post	1,000
SF General Hospital	4/25/2019	Richmond District Neighborhood Center	C: Brochure/Poster/Flyer distribution	50
SF General Hospital	4/29/2019	Bernal Hill Neighborhood Center	C: Brochure/Poster/Flyer distribution	25
SF General Hospital	5/13/2019	Capp Street Senior Center Spanish language	C: Brochure/Poster/Flyer distribution	50
SF General Hospital	4/5/2019	Mission Neighborhood Health Center	C: Brochure/Poster/Flyer distribution	50
SF General Hospital	3/31/2019	Sunday Streets Excelsior-Spanish. Community streets open to pedestrians/bicyclists	C: Brochure/Poster/Flyer distribution	8
SF General Hospital	3/31/2019	Sunday Streets Excelsior English. Community streets open to pedestrians/bicyclists	C: Brochure/Poster/Flyer distribution	26
SF General Hospital	4/4/2019	Curry Senior Center	C: Brochure/Poster/Flyer distribution	25
SF General Hospital	4/4/2019	Aquatic Park Senior Center	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	4/14/2019	Mission Neighborhood Centers	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	4/14/2019	Sunday Streets Tenderloin Neighborhood open to pedestrians/bicyclists	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	4/25/2019	Bay Area Reporter	B: Newspaper ad/article	17,000
SF General Hospital	5/5/2019	Sunday Streets Bayview/Dog Patch. Neighborhood streets closed to traffic for pedestrians/bicyclists	C: Brochure/Poster/Flyer distribution	10
SF General Hospital	4/25/2019	Castro Senior Center	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	4/26/2019	Univ. of California San Francisco General Hospital Neuro/neurosurgery clinic waiting room-Spanish	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	4/26/2019	Univ. of California at San Francisco General Hospital Neuro/Neurosurgery clinic waiting room-English	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	5/2/2019	University of California San Francisco Medical Center Parnassus Neurology Clinic Waiting Room	C: Brochure/Poster/Flyer distribution	50
SF General Hospital	5/8/2019	Brain and Spinal Injury Center University of California San Francisco Facebook Page	A: Social media website/post	100
SF General Hospital	5/8/2019	University of California San Francisco Brain and Spinal Injury Center Tweet	A: Social media website/post	100
SF General Hospital	5/13/2019	Capp Street Senior Center English	C: Brochure/Poster/Flyer distribution	50
SF General Hospital	4/30/2019	San Francisco Police Department Station Community Room Brochure Distribution	C: Brochure/Poster/Flyer distribution	30
SF General Hospital	5/2/2019	San Francisco General Hospital Traumatic Brain Injury Support Group	C: Brochure/Poster/Flyer distribution	14
SF General Hospital	5/23/2019	Glide Social Justice Multi Service Program	C: Brochure/Poster/Flyer distribution	100

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:

- UCSF at Zuckerberg SF General Hospital
- Stanford University Medical Center

Contact Us

BOOST3 Study

Zuckerberg SF General Hospital
1001 Potrero Avenue
San Francisco, CA 94110

Jeany Duncan Coordinator

Phone: 415-206-4106

E-mail: jeany.duncan@ucsf.edu



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 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.

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 "Exception from Informed Consent" (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.

Buttigieg dodges GOP attack at town hall

by Lisa Keen

The loudest and most sustained applause for gay presidential candidate Pete Buttigieg during a CNN town hall Monday night came for his politically unorthodox response to a recently launched attack on him by the Trump administration.

CNN moderator Anderson Cooper, who is also gay, broached the subject with just a few minutes left in the one-hour forum, which had been preceded by one-hour forums with each of four other Democratic presidential candidates.

Although in previous venues, Buttigieg had mentioned his dismay with Vice President Mike Pence's long-standing, well documented record of opposing equal rights for LGBT people, this time, he criticized President Donald Trump for his "chest thumping and self-aggrandizing, not to mention abusive behavior. ..."

Cooper noted that Buttigieg had gotten into a "back-and-forth" recently over his criticism of Pence. (Pence's wife tried to dismiss Buttigieg's portrayal of the vice president as anti-gay as a campaign gimmick "to get some notoriety." A Pence spokesperson noted that, when Buttigieg came out publicly as gay, then-Governor Pence said he held Buttigieg "in the highest personal regard.")



Courtesy CNN

Democratic presidential candidate Pete Buttigieg discusses issues during a CNN town hall Monday night in New Hampshire.

Now, said Cooper, "the current ambassador to Germany, Richard Grenell, who is also gay, weighed in" on the row. Grenell, said Cooper, has been "saying you have been 'pushing this hate hoax [about Pence] along the lines of Jussie Smollett for a very long time now, several weeks? How do you respond to that?" (Gay actor Smollett garnered considerable negative media attention recently when he was accused of filing a false report of an anti-gay assault against him. The charges were later dropped.)

Buttigieg did not hesitate.

"I'm not a master fisherman," said Buttigieg, "but I know bait when I see it, and I'm not gonna take it."

The audience erupted in sustained applause and cheers. Cooper moved on, but the newcomer had dodged his first political Molotov cocktail from a surrogate for President Donald Trump, a Goliath of insults.

Monday night's event with Buttigieg was his second nationally televised town hall forum on the cable network. The first such forum, in March in Austin, Texas, boosted Buttigieg from a virtual unknown on the national political stage to a top tier contender for the Democratic nomination for president. The latest national poll, released April 23, showed him in third place among Democratic contenders nationwide (as well as in early primary states), with name recognition of 64%. (The poll of 1,992 registered voters by Morning Consult was conducted April 19-21, with a margin of error of plus-or-minus 1%.)

The April 22 forum seemed to position Buttigieg for continued success.

"CNN's town hall Monday night in New Hampshire was the clearest sign yet that South Bend Mayor Pete Buttigieg is a candidate who's still catching up to his own popularity," said the lead in CNN's coverage of the forum.

But while the audience of area college

students gathered at St. Anselm College in New Hampshire clearly liked Buttigieg, the forum wasn't a cakewalk.

Buttigieg also dodged a legitimate question raised by New England College student Trevor VanNiel, who asked, "How would you cooperate with countries that view homosexuality as a sin and a crime that is punishable by death?"

"Well, I think it's wrong to harm or punish people because they are part of the LGBTQ community," said Buttigieg. "I get that not every country is there. In some dramatically milder respects but very still bothersome ones, our own country is not there. I believe this is an example of why the world needs an America that is strong, that's credible, and that people believe keeps its word because, frankly, our ability, and the ability of the next president and of the U.S. to lead on this issue, I mean to really try to guide countries toward doing the right thing, largely depends on whether we have any moral authority at all."

Buttigieg said America's moral authority today has "plummeted."

"And whether it's LGBTQ rights or, frankly, any kind of human rights or democracy promotion that we want to advance ... it's really important for the U.S. to be a credible messenger,"

he said, before wandering into a discussion of "different models" of government around the world.

Most of the other Democratic candidates at the forum Monday night — Senators Bernie Sanders (Vermont), Elizabeth Warren (Massachusetts), and Amy Klobuchar (Minnesota) — were not asked LGBT-related questions.

Senator Kamala Harris, who appeared before Buttigieg, did respond to a question on LGBT rights by stating that she refused to defend California's Proposition 8 anti-same-sex marriage ban when she served state attorney general. (Prop 8 was later thrown out by the U.S. Supreme Court, legalizing same-sex marriage in the Golden State in 2013.)

Harris also pointed out that, in San Francisco's district attorney, she convened a symposium for judges to learn how to combat so-called gay- and trans-panic defenses, a legal strategy that asks a jury to find that a victim's sexual orientation or gender identity is to blame for the defendant's violent reaction, including murder.

Fox News announced Tuesday that it has scheduled a town hall in Claremont, New Hampshire, with Buttigieg Sunday, May 19. The program will be broadcast live beginning at 4 p.m. Pacific Time. ▼

Catholic foster care agency loses case against Philly

by Lisa Keen

For the first time, a federal appeals court has ruled that a local government can exclude a child foster care agency from city-funded programs if the agency refuses to abide by a local ordinance that prohibits discrimination based on sexual orientation.

In *Catholic Social Charities v. Philadelphia*, the Catholic-run child place-

ment group tried to claim an exemption to the city's non-discrimination law by contending its refusal to place children with same-sex couples was based on its religious beliefs. But a three-judge panel of the 3rd U.S. Circuit Court of Appeals said Monday, April 22, that the agency's religious views did not entitle it to an exemption from the city's non-discrimination law.

"The city's non-discrimination

policy is a neutral, generally applicable law, and the religious views of CSS do not entitle it to an exception from that policy," stated the panel. The judges said CSS had failed to make a "persuasive showing that the city targeted it for its religious beliefs, or is motivated by ill will against its religion. ..." The judges said the non-discrimination law was based on the city's "sincere opposition to discrimination on the

basis of sexual orientation."

The panel included Judges Thomas Ambro (a Clinton appointee), Anthony J. Scirica (Reagan), and Marjorie Rendell (Clinton).

The American Civil Liberties Union, which was an intervenor on behalf of LGBT parents in the case, declared victory.

"This is a victory for the thousands of children in Philadelphia's child welfare system," said Leslie Cooper, director of the ACLU's national LGBT Project. "... Prospective foster and adoptive parents should be judged by their capacity to provide love and support to a child, not the religious views of a tax-funded agency."

Religious views, said Cooper, do not "entitle taxpayer-funded child welfare agencies to impose their own religious eligibility criteria on important government programs."

The religious-based legal advocacy group Becket, which led the lawsuit on behalf of CSS and several foster parents who used CSS, expressed disappointment with the ruling and said it was weighing its options for appeal.

"This ruling is devastating to the hundreds of foster children who have been waiting for a family and to the dozens of parents working with Catholic Social Services who have been waiting to foster a child," said Lori Windham, senior counsel at Becket. "We're disappointed that the court decided to let the city place politics above the needs of kids and the rights of parents, but we will continue this fight."

The conflict in Philadelphia mirrors that in some other major cities, including Boston and Lansing, Michigan, where child placement agencies run by religious-based groups have sought government funding for their work but have refused to abide by local or state laws prohibiting discrimination based on sexual orientation. It also exacerbates a growing crisis in many cities and states that are experiencing an increased number of children needing placements — sometimes on an emergency basis — due to the opioid crisis.

Just two months ago, President Donald Trump expressed support for allowing adoption and foster care agencies that discriminate against LGBT people to claim a religious exemption. And the U.S. Department of Health and Human Services under Trump granted South Carolina a



Judge Thomas Ambro

waiver that allows it to funnel federal funds to foster care agencies that discriminate against LGBT people and people of certain religions.

In Philadelphia, the city Department of Human Services learned that two child placement agencies receiving funds from the city were refusing to place children with same-sex couples who were willing to serve as foster parents. When confronted, the two agencies claimed they were acting on their religious beliefs. The city did not challenge that claim but stopped referring children to the two groups.

One of the groups, CSS, filed a lawsuit, claiming its First Amendment right to free exercise of religion was being violated. A district court judge ruled against CSS's request for a preliminary injunction and the appeals panel upheld that ruling. Typically, the case would go back to district court for a hearing on the First Amendment issues raised by CSS. The group could choose to ask the appeals court bench for a hearing even go directly to the U.S. Supreme Court with a petition.

A similar dispute in Massachusetts ended with Catholic Charities pulling out of state-funded child placement programs. In Michigan, a federal judge ruled against St. Vincent Catholic Charities last September, saying a lawsuit on behalf of the same-sex couples by the ACLU could proceed against a state policy allowing adoption agencies to discriminate if agencies claim such adoptions would violate their religious beliefs. The conflict is still under litigation, another faith-based child placement group in Michigan announced Monday it would end its policy of excluding same-sex couples. ▼



University of California San Francisco

A study of emergency care involving victims of severe brain trauma is to be performed in this area.

Traumatic brain injury is the leading cause of death and disability in children and adults up to 44 years of age. Every 15 seconds someone in the US suffers a major traumatic brain injury, and every five minutes someone is forever disabled from traumatic brain injury.

UCSF at Zuckerberg San Francisco General Hospital 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. 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 on preventing high intracranial pressure caused by a swollen brain. In the other strategy doctors try to prevent high intracranial pressure and also try to prevent low brain oxygen levels. This study will discover if either strategy is more safe and effective.

The study will include adults and children older than 14 years with severe brain injury requiring admission to the ICU with brain monitoring. Hospitals across the country are conducting the study which is funded by the US National Institutes of Health.

Because head injury is a life threatening condition requiring immediate treatment, some patients will be enrolled without consent if a family member or other representative is not rapidly available. Every attempt will be made to locate family prior to enrollment to allow them to decide about the patient's participation in the study.

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 415-206-4106



Primary Investigator: J. Claude Hemphill, MD
Study Coordinator: Jeany Duncan jeany.duncan@ucsf.edu

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JUUL hires campaign consultants, hinting at big-money ballot fight to come over vape ban

**JOE FITZGERALD
RODRIGUEZ**
ON GUARD



Heavy-hitting lobbyists and campaign consultants recently hired by vape giant JUUL hint at a big-money ballot measure to overturn Supervisor Shamann Walton's proposed vape ban, should it pass, insiders tell me.



Walton

The purveyors of puff plan to start by playing nice.

JUUL has hired lobbyist Chris Gruwell, CEO of New Deal Advisers to be their inside man. No doubt he'll play a key role contacting supervisors and arguing for a vote against Walton's ban, or some way to scuttle it before it ever gets that far.

Gruwell is experienced as they come, and represents beloved local transit company Scoot, not-so-beloved "disruptive" scooter company Bird, property management firm Boston Properties and the San Francisco Chronicle's publisher Hearst Corp., among others.

When and if his effort fails, JUUL's next three hires step up to the plate: David Ho, Nate Albee and Mark Mosher, campaign consultants extraordinaire.

Their specialty, their vocation, their *raison d'être*, if you will, is ensuring San Franciscans vote for their client — which suggests JUUL may be keeping a ballot measure in their back pocket. After all, you don't buy a gun unless you're thinking about shooting it.

In an interview Friday, Ho admitted as much to me.

"Right now there's no campaign, unless we can't come to a compromise," Ho said. "I'm assuming they're getting loaded, locked and ready to go."

If I were Walton, I'd be quaking in my boots about now.

Luckily for those who care about the health of children who are reportedly getting hooked on vape pens, Walton ain't me. In a phone conversation Friday, Walton sounded resolute: He will move forward with a vape ban despite any threatened ballot measure.

"It sounds like that's what JUUL's gearing up to do," Walton speculated. "But most irresponsible companies aren't happy when you try stop them from harming young people."

And for those who marvel at the insidious wonkery that is San Francisco politics, this marks the first time that Ho and Albee — who are usually on opposite sides — will join forces since they worked together briefly on Supervisor Aaron Peskin's comeback supervisorial campaign in 2015.

Ho ran the independent expenditure committee supporting London Breed's winning mayoral run. Albee supported Mark Leno and Jane Kim.

Ho stumped for candidate Christine Johnson. Albee worked for Supervisor Matt Haney, who cleaned Johnson's clock.

And Ho was the iron knuckle behind Supervisor Ahsha Safai's winning campaign, whereas Albee supported Kimberly Alvarenga, who lost by a hair.

Ho says toe-may-to, Albee says to-mah-to. You get the picture.

Now the moderate and progressive-supporting odd couple is all peaches and cream. All it took was a little nudge from the tobacco industry.

Ain't politics grand?

OK, raise your hand if you popped some popcorn and watched, slack-jawed, as privileged, tone-deaf waterfront neighbors lambasted Mayor London Breed for *daring* (and I mean, *the nerve!*) to put a homeless navigation center near their sea-blue views at Seawall Lot 330.

I tell you, the town hall meeting that Wednesday night, April 3, was hilarious in its absurdity, and saddening in its predictability. Still, as a born and raised San Franciscan, it rattles me that people could be so cruel to the suffering at their doorsteps.



COURTESY PHOTO

E-cigarette company JUUL has hired big-time lobbyist Chris Gruwell.

But I ain't about mopin'. I sought a cure for what ailed me, and found it, in a public records requests of Mayor London Breed's emails. And Eureka! Lo and behold! Those emails revealed something truly stunning to me: There are actually waterfront neighbors who *want* the navigation center to move near their homes.

After that stunner of a waterfront meeting, roughly 39 people emailed Breed opposing the navigation center, but a not-too-shabby 34 people wrote her in support of it. Some even live and work nearby. I'm withholding their names due to the high-intensity hate that's been zinging about this issue, but am quoting them below so we can all see that support.

One resident — who is also a YIMBY member — said their romantic partner works "two blocks away" from the proposed navigation center, and that they both have children who will soon attend daycare near it. This resident wrote to Breed that "the expansion of navigation center capacity will improve the experience of children all over our city who encounter troubling street behavior on a daily basis."

They added, "there is absolutely nothing wrong with this site."

A Rincon Hill resident who lives one block from the proposed navigation center said she is the mother of a toddler. "I am in SUPPORT of this navigation center because I believe we need to do everything possible to combat the severe inequality in this city," she wrote.

And last but far from least, a twenty-year resident of the neighborhood wrote in support of the

navigation center, even though they live just three blocks away from the proposed site.

Of the rude shouting and yelling from the community on Wednesday, this resident wrote, "I searched the faces of those around me, trying to see if anyone felt empathy for the people who were the subject of this project. I didn't find many."

Yet I found empathy in her words, and the words of many San Franciscans who want this project to go forward.

And sometimes a little empathy is all you need.

On Guard prints the news and raises hell each week. Email Fitz at joe@sfxaminer.com, follow him on Twitter and Instagram @FitztheReporter, and Facebook at [facebook.com/FitztheReporter](https://www.facebook.com/FitztheReporter).

A study of emergency care involving victims of severe brain trauma is to be performed in this area.

UCSF at Zuckerberg SF General Hospital 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

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Study Coordinator: Jeany Duncan

UCSF

University of California
San Francisco

 **BOOST-3**



(<https://brainandspinalinjury.org>)



 (415) 206-8300 (tel:1-415-206-8300)

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The researchers at BASIC have conducted numerous other smaller scale studies with the aim of improving the care and outcome of patients with traumatic brain injury, spinal cord injury

and other neurosurgical disease processes.



Brain Oxygen Optimization in Severe TBI Phase-3

A new study called BOOST3 will be starting at Zuckerberg San Francisco General Hospital and approximately 45 trauma centers in the United States in the summer of 2019. Please see the study summary below with the accompanying link to the study website if you'd like more information.

If you'd like to participate by filling out an anonymous survey regarding BOOST3, go this link. <http://bit.ly/BOOST3CommunitySurvey> (<http://bit.ly/BOOST3CommunitySurvey>)

Thank you! And if you have any questions or concerns, please see the local study contact information below:

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Primary Investigator: Claude Hemphill MD

Study Coordinator: Jeany Duncan

Jeany.duncan@ucsf.edu

University of California

San Francisco

SF-NETT Projects

Dr. Claude Hemphill and his colleagues at San Francisco General Hospital and UCSF are one of 17 academic centers selected as a "hub" for the NETT. Each hub acts as a local coordinating center for other participating hospitals, known as "spokes." The hub of SF-NETT is in the Brain and Spinal Injury Center (BASIC) at San Francisco General Hospital. Spoke hospitals include all San Francisco



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University of California
San Francisco
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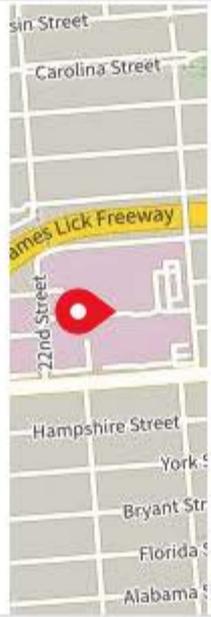
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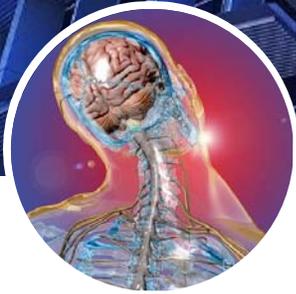
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Pursuing outstanding patient care and world-class research to achieve a better understanding of treatment for traumatic brain and spinal cord injuries.

 [San Francisco, CA](#)

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 Joined January 2018



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UCSF-Brain and Spinal Injury Center @UCSF_BASIC · 3h

A new study called BOOST3 will be starting at [Zuckerberg San Francisco General Hospital](#) and approximately 45 trauma centers in the United States. If you'd like to participate by filling out an anonymous survey regarding BOOST3, go this link. bit.ly/BOOST3Community



2

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UCSF-Brain and Spinal Injury Center @UCSF_BASIC · Apr 30

Congrats to [@UCSF_BASIC](#) PI [@rosi_susanna](#) for having yet another research proposal funded by [@NASA](#). The proposal aims to address how radiation, altered gravity and stress can predict performance decrement in astronauts. Can't wait for the exciting results!

New Study Selections on Astronaut Adaption to Moon and Mars Miss...

Missions to destinations like the Moon or Mars will demand astronauts adapt to the many hazards the human body will have to endure.

nasa.gov



4



UCSF-Brain and Spinal Injury Center @UCSF_BASIC · Apr 25

Yesterday we celebrated [#DNADay](#) and [@Invitae](#) made a nice poll on SF streets. We can do better San Francisco!



1



UCSF-Brain and Spinal Injury Center @UCSF_BASIC · Apr 24

Happy National DNA Day!!! Here at [@UCSF_BASIC](#) genomics is a great part of our research towards better understanding and treating TBI and SCI! At the same time it is our duty to raise public awareness about the great potential of genomic research. [#DNADay19](#) [#NationalDNADay](#)

illumina @illumina

Genomics is helping solve some of the most challenging problems of humankind and inspiring new hope for people around the world. Yet, a new

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本地區嚴重腦創傷病人 將被納入急救治療研究

三藩市加大 (UCSF) 正在朱克伯格三藩市總醫院進行一項研究，研究在深切治療部 (ICU) 對嚴重腦創傷病人進行監測和治療的兩種策略中，哪一種對病人更有幫助。由於頭部創傷威脅到生命，必須立即救治，對於有些病人，如果無法迅速聯繫到其家人，醫院會在沒有得到同意的情况下將病人加入這項研究。在研究開始之前，我們將諮詢社區。我們歡迎您的反饋和提問。

您也可以前往網站 boost3trial.org 或致電我們的工作人員了解研究計劃詳情，或拒絕參與這項研究。

電話：415-206-4106
項目負責人 Claude Hemphill MD
研究協調員 Jeany Duncan
電郵 Jeany.duncan@ucsf.edu



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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 information the site wanted to share.

Local Context responses

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

White alone 47-53%, Black or African American alone 5.3-5.5%, Asian alone 34.2-35.9, American Indian/ Alaska Native 0.4-0.7%, Two or more races 5.1-4.3%, Hispanic or Latino 15.3-15.2%, White alone, not Hispanic/Latino 40.8-40.5 %

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.):

SF has a large homeless/mentally ill population. There is also a large population of immigrants from southern China that are Cantonese/Toisanese speaking.

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.):

California requires the use of its Bill of Rights.

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):

No, study team is experienced at EFIC and is doing all the community outreach.

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.

Our activities showed respect for persons by seeking and engaging in meaningful dialog in groups as well as one on one interactions, by talking with people on their own turf when invited, by offering to do presentations if requested by the organizations we provided brochures to and by talking about research at other events.

We also placed ads in San Francisco English, Spanish, Chinese and LGBTQ newspapers.

We ensured that the activities provided a means for affected communities to provide input by meeting with people of diverse ages, backgrounds, race, ethnicity, medical risk and experience. We were particularly cognizant, respectful and inclusive of the economic extremes in San Francisco. We met with TBI survivors, the SF Motorcycle Club, SF paramedics, public community groups and formerly homeless veterans in order to accomplish this. The age range on our surveys was 24-78 years of age.

We showed respect for individuals who have, or may be at greater risk for TBI by talking to motorcycle clubs and TBI support groups. The study team also reviewed stats regarding age in prior TBI studies which showed the majority of TBI patients are over 50 years of age. Our CC/PD activities reflect this age demographic.

Some take away messages from our CC/PD gleaned from the quantitative and qualitative data detailed in this report are 1. There is widespread support for BOOST3 and EFIC research. A majority of those learning about this research would be willing to participate if they suffered a TBI.

2. EFIC research is a challenging concept for the public to comprehend. As basic an explanation as possible should be given at the outset with as much time as possible given to answering questions.

3. An inadvertent benefit from the EFIC process was a stronger connection to the TBI community in SF. Meeting veteran outreach workers and a paramedic with prior military acquired IED TBI histories reinforced the need for this research. Multiple people in other venues shared their TBI stories and seemed relieved to know they were speaking with somebody that "gets it".

Subjective take away knowledge is that EFIC research is a challenging concept for the public to comprehend. As basic an explanation as possible should be given at the outset with as much time as possible given to answering questions.

The concerns we heard were relatively infrequent and mostly involved any type of research without consent if the person is/were a parent whose child had a brain injury. No recommendations for changes to study conduct were received from the community.

Total Population		884,363
White alone	47-53%	
Black or African American alone	5.3-5.5%	
Asian alone	34.2-35.9%	
American Indian Alaska Native	0.4-0.7%	
Two or more races	5.1-4.3%	
Hispanic or Latino	15.3-15.2%	
White alone, not Hispanic/Latino	40.8-40.5 %	

Age and Sex		
Persons under 5 years		4.50%
Persons under 18 years		13.40%
Persons 65 years and over	14.9-15.4%	
Female persons		49%

Foreign Born Persons		34.80%
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Education		
HS Graduate or Higher age 25+		87.90%
Bachelors degree or higher 25+		55.80%

Median Age in San Francisco		
Both Sexes		38
Male		38
Female		38

*Data from US Census Bureau

EFIC Packet – SF General Hospital

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