**Results of Community Consultation and Public Disclosure Efforts in the “Established Status Epilepticus Treatment Trial”**

**Introduction**

A detailed outline of the community consultation and public disclosure plan was developed in cooperation with the IRB and approved for implementation. This document, titled “*PCH ESETT EFIC Plan Proposal Ver. 1.doc*” can be accessed in the ERICA system for the Utah IRB and is uploaded in the regulatory documents section in the WebDCU database for the central site access. The key points of the plan include:

1. Community Consultation

1. Local seizure groups consisting of parents and formal leaders of the community will be conducted.
2. A meeting open to the public and to those affected by seizures will be conducted.
3. A regularly occurring meeting held by the neurology department will be attended and information regarding the ESETT study will be presented.
4. Presentation to health professionals during regularly scheduled lecture series at the Division of Pediatric Emergency Medicine.
5. Individual feedback surveys will be utilized and distributed in the ED via iPad. Individual respondents will complete surveys after viewing a brief video presentation of study materials.

2. Public Disclosure

1. In-hospital postings including flyers, posters, and brochures available in the ED and neurology clinic.
2. Distribution of flyers or brochures at local community events such as fundraisers and awareness events.
3. Electronic resources include social media posts uploaded by seizure related groups such as the Epilepsy Alliance of Utah and the Epilepsy Association of Utah, directing the public to www.esett.org for more information about the study.
4. A central website, www.esett.org, is available to the public for general information regarding study procedures and opt-out information.

**Methodology**

***Community Consultation at Existing Meetings:***

Attendance to existing meetings were dependent upon the scheduled times set forth by the organization hosting the event. With permission of the participants, audio recordings were gathered at all community consultation events to review the discussions that occurred and to be available to the IRB or study coordinators for future reference. Surveys were distributed at all of these community consultation events with an option to “opt-out” of the study.

1. May 6, 2015 – Division of Pediatric Emergency Medicine: Research Conference
Presenters: Maija Holsti, MD, MPH, ESETT Principal Investigator, Kammy Jacobsen, ESETT Research Manager, Michael Dela Cruz, CRC, Dilon Stephens, CRC
Number of Attendees: 18

This was a preliminary meeting presented to the physicians in the Emergency Department at Primary Children’s Hospital. Physicians were given an introduction to the ESETT study. Physicians themselves did not take the individual feedback survey, but were shown the content that prospective participants would be exposed to. The purpose of this meeting was to let physicians know that the study qualified under “Exception From Informed Consent”. Concerns were raised regarding the unblinding of the study drug, specifically regarding the process of how unblinding was to be done and at what time. Study wide, all sites had similar feedback regarding the unblinding procedure and deliberations via phone conferences were held to address this issue. It was later finalized and distributed to all sites that a protocol assist device would help physicians easily unblind the study drug.
2. May 20, 2015 – Epilepsy Alliance of Utah at Salt Lake City Library conducted in English

Presenters: Maija Holsti, MD, MPH, ESETT Principal Investigator, Kammy Jacobsen, CCRC, ESETT Research Manager, Michael Dela Cruz, CRC, ESETT Program Coordinator.

Number of Attendees: 8

We presented to a support group of adults, who themselves had seizures. The purpose of these established meetings by the organization is to provide assistance for those affected by epilepsy, adults and families with children, through support, job training, and personal rights advocacy. Discussions after the presentation and survey administration revealed 87% of the participants were supportive of the ESETT study. Two participants surveyed chose to opt out of the study. Clarification on the use of the seizure study medications as a rescue dose versus maintenance dose was addressed. These concerns were then integrated for future presentations to anticipate similar concerns. Compensation was offered in the form of refreshments.

1. June 23, 2015 – ESETT Study Introduction to Executive Board of Epilepsy conducted in English
Presenters: Doug Nelson, MD, PECARN Site Primary Investigator, PECARN Steering Committee Member, PECARN Feasibility and Budget Committee, Kammy Jacobsen, CCRC, ESETT Research Manager, Michael Dela Cruz, CRC, ESETT Program Coordinator.
Number of Attendees: 4

A presentation was given to the executive members of the Epilepsy Association of Utah. The executive board organized this meeting to determine if the ESETT study was appropriate to present to other meetings the Epilepsy Association of Utah sponsored. These community leaders spoke in behalf of its members who consisted typically of parents of children who experienced seizures intermittently or acute chronic cases. Survey feedback results revealed that 100 % of the participants were supportive of the ESETT Study. Discussions after presentation of the study revealed concerns about unblinding of the study seizure drug after enrollment. Dr. Nelson addressed this concern and clarified that the drug could be unblinded before the 60-minute wait time suggested by the protocol. Two participants opted out.

1. August 5, 2015 – ESETT Study Introduction to Primary Children’s Hospital, Neurology Department conducted in English
Presenters: Maija Holsti, MD, MPH, ESETT Principal Investigator, Kammy Jacobsen, CCRC, ESETT Research Manager, Michael Dela Cruz, CRC, ESETT Program Coordinator.
Number of Attendees: 22

This event was held at a regularly scheduled neurology meeting at Primary Children’s Hospital. The purpose of the meeting was to let physicians and other healthcare professionals treating pediatric patients diagnosed with seizures, be aware of the upcoming seizure study at the Emergency Department. An IRB representative was present at this meeting. Discussions after the presentation of the ESETT study and survey distribution revealed that 86% of participants supported the study. Two participants requested for their child to be added to the opt-out list. One concern that came up by one of the Neurologist that was sent to the central site:

1. The contraindication of Fosphenytoin in children diagnosed with Dravet Syndrome.

Response from Neurologist at central site:
 “Fosphenytoin and other sodium channel blockers are not used in the prevention of chronic myoclonic epilepsies in Dravet because they can make them worse. Fosphenytoin is still the mainstay of treating benzodiazepine refractory status epilepticus. This is more of a concern for chronic dosing but not as much a concern for a single dose of Fosphenytoin in the study."

\*This response was forwarded to the neurologist who raised the concern.

1. August 13, 2015 – Epilepsy Association of Utah South Jordan Library Meeting conducted in English
Presenters: Maija Holsti, MD, MPH, ESETT Principal Investigator, Dilon Stephens, CRC, ESETT Team Leader, Michael Dela Cruz, CRC, ESETT Program Coordinator
Number of Attendees: 15

The Epilepsy Association of Utah organized a meeting open to the public as well those of the seizure community. There were some attendees, specifically from the executive board of the Epilepsy Association of Utah, who previously attended ESETT meetings. Executive members who were not present at the initial executive board meeting attended as well. IRB representatives were present at this meeting. Also, present was a community Neurologist.

Results of the individual feedback survey revealed that 100% of the participants supported the ESETT Study. Four participants asked for their child to be added to the opt-out list. The majority of those who opted out had a child who had an allergy to one of the study seizure medications. Dr. Holsti addressed concerns regarding retrospective studies, procedures for unblinding, and the ease and function of the esett.org website. Importantly, parents expressed concerns about personalized care plans that might be affected by the study. Dr. Holsti assured these parents that the study will not interfere with personalized care plans and will be honored. These concerns were revisited via audio recordings of the meeting. The presentation for subsequent meetings was modified to incorporate new concerns. The Neurologist present at this meeting had two questions that were sent to the central site and are addressed below:

1. *“If the patient is on lamotrigine and you want to add Depakote, their lamotrigine dose has to be decreased by 50% to avoid rapid rise in lamotrigine level that is associated with Stevens Johnson. Is being on lamotrigine going to disqualify a patient from the study?*

Response from Neurologist at central site:

 “The data on the interaction between LTG and VPA are for chronic dosing and not for a single dose. So, while if on LTG and randomized to VPA, this is a very legitimate concern in both children and adults, we would likely not then continue treating with VPA without dose adjustments. LTG is not an exclusion for a single dose in the study.”

1. *Higher doses of Depakote are associated with thrombocytopenia in a dose dependent manner. If a patient is already taking Depakote, and especially if their levels are high, would a 20mg/kg IV bolus dose place them at excess risk of dose-dependent thrombocytopenia?"*

Response from Neurologist at central site:

 “Platelet reduction is not a significant concern with a single dose. If there are effects on platelets, it is transient. We do not feel that this will place them at excess risk for thrombocytopenia. There is a medical safety officer and a DSMB for this study that will able to identify this, should it occur. This is more of a concern for chronic dosing but not as much a concern for a single dose of Valproic Acid in the study.”

\*These responses have been forwarded to the neurologist who raised the concerns.

1. September 1, 2015 – ESETT Study Presentation to Executive Board of Epilepsy

Presenters: Maija Holsti, MD, MPH, ESETT Principal Investigator, Dilon Stephens, CRC, ESETT Team Leader, Michael Dela Cruz, CRC, ESETT Program Coordinator.
Number of Attendees: 9

Per request of formal community leaders present at the August 13th meeting, another presentation was given to more members of the executive board of the Epilepsy Association of Utah. Survey results revealed that 100% of the participants were supportive of the ESETT Study. Executive board members who attended previous meetings appreciated the modifications made to address concerns they had in the past.

***Surveys***

In addition to attending pre-existing meetings, individual feedback surveys were distributed in the Emergency Department of Primary Children’s Hospital and 615 surveys were completed. Research Assistants from the Academic Associate Program presented the ESETT study to low acuity patients and their families. Consent cover letters were given to participants who were interested in learning about the study. An iPad was used to present the study. At the end of the electronic presentation, participants clicked on a link to complete the individual feedback survey. The option to opt-out of the study was available in the survey form.

Link to “Prezi” presentation: <https://prezi.com/ofn4g7yofvxq/the-esett-study/?utm_campaign=share&utm_medium=copy>

Link to survey (available at end of “Prezi” presentation): <https://redcap01.brisc.utah.edu/ccts/redcap/surveys/?s=ujNW6pbEsh>P

\*See attached hard copy document titled “ESETT Feedback Questionnaire”

***Summary of Results***

\*Please see attached PDF document (ESETT Community Consultation Survey REDCap.pdf) for a detailed statistical analysis of the individual feedback survey results.

Survey results reported are from all Community Consultation activities that include “Prezi” presentation with survey on the iPad and paper surveys distributed at meetings.

TotalSurveys Completed: **615**
Total participants in Opt-out List: **44**

Note: Individual surveys may have some discrepancies (i.e. some participants did not answer all the questions).

“*ESETT is an important study to do.”*

* 85.4% (525) Strongly Agree or Agree
* 13.8% (85) Neutral
* 5.3% (5) Strongly Disagree or Disagree

 “*If you developed a seizure that would not stop, you would be okay being included in ESETT without giving your consent ahead of time*?”

* 76.1% (466) Strongly Agree or Agree
* 15% (92) Neutral
* 8.8% (54) Disagree or Strongly Disagree with this scenario

*“If you are/were a parent and your child developed a seizure that would not stop, you would be okay with him/her being included in ESETT without giving your consent ahead of time?”*

* 73.2% (447) Strongly Agree or Agree
* 13.7% (84) Neutral
* 13% (80) Strongly Disagree or Disagree

“*Do you think that ESETT researchers will seriously consider what community members, like you, have to say about this study before starting it?”*

* 69.5% (427) Yes
* 6.5% (40) No
* 24.3% (149) I Don’t Know

The individual feedback surveys provided participants with a comment section to present any concerns they had about the study. General consensus revealed a positive appreciation for the purpose of the study. Some participants had concerns for their child’s allergic reaction to the study drug. The issue of allergies has been addressed in community consultation events and parents have been advised to add their child’s name in the opt-out list.

***Public Disclosure***

Public disclosure efforts were completed in collaboration with local organizations such as the Epilepsy Alliance of Utah and Epilepsy Association of Utah. These local groups posted information on Facebook about upcoming ESETT meetings as well as links to the central site for their members to access. Meetings with the public relations department of the University of Utah and Primary Children’s hospital occurred to discuss co-branding of ads, brochures, and flyers to be distributed to the public. Public disclosure efforts will be an ongoing process involving Research Assistants from the Academic Associate Program distributing brochures in the Emergency Department at Primary Children’s Hospital. We will continue public disclosure activities throughout the duration of this study and any community consultation events upon request.

1. May 20, 2015 – Epilepsy Alliance of Utah Facebook Ad

People reached: Unknown

This was a Facebook Ad alerting the public of an upcoming meeting to be presented by Dr. Holsti was posted. A short summary of the ESETT study was posted on the group’s page as well.

1. May 20, 2015 – Epilepsy Alliance of Utah, Epilepsy Foundation: An Evening of Celebration Gala 2015
People reached: 109
The board president of the Epilepsy Alliance of Utah collaborated with the ESETT study team to determine which tables at the gala event would be appropriate to distribute brochures to. She advised us to print 109 brochures for her to distribute to tables sponsored by the U of U College of Pharmacy, U of U Medical Center, Intermountain Medical Center, and pharmaceutical companies (Lundbeck, Inc., Upsher-Smith, Sunovion, and Cyberonics).
2. August 13, 2015 – Epilepsy Association of Utah Facebook Ad
People Reached: 107
The Epilepsy Association of Utah sponsored a meeting for the ESETT study at the South Jordan public library. Prior to this event a Facebook Ad was placed on their group page. The number of people that were exposed to the site’s ad was displayed on the group’s page. 107 individuals were reached.
3. August 13, 2015 – ESETT Poster display in Emergency Department
People Reached: Unknown
The ESETT poster is displayed in a high traffic area for healthcare professionals and public. It is located in the main hallway to the left of the main entrance of the Emergency Department. Faculty, staff, and patients frequent this location as access to the consult room, pharmacy, and the cafeteria. Poster contains summary of study purpose and contact information for inquiries.
4. August 24, 2015 – ESETT Brochures distributed by Research Assistants of the Academic Associates Program.
People Reached: 69\*
Research Assistants screen and approach low acuity patients in the Emergency Department to distribute flyers. A log is maintained weekly to account for the number of people who received ESETT brochures. As of August 24, 2015, 69 people were approached and received a brochure.

\*This number is anticipated increase over time as this is an ongoing effort that will last the duration of the study.

1. September 12, 2015 – “Seize The Night” 5k Run by the Epilepsy Alliance of Utah
People Reached: 125
The board president of the Epilepsy Alliance of Utah collaborated with the ESETT study team to determine the number of brochures needed for this event. 125 brochures were requested at the event to be placed in bags provided by one of their sponsors, Cyberonics.