

ESETT INVESTIGATOR MEETING

EFIC & ENROLLEE/SURROGATE SURVEY

SEPTEMBER 18, 2015

Deneil M. Harney, MPH, MSW

HSP / EFIC Specialist

University of Michigan



Agenda

1. Documenting EFIC Activities

CC Form

PD Form

2. CC Report

3. Enrollees' and Surrogates' Attitudes Survey



Help

Enrolled 23% (23 / 100) of Projected Subjects

Subject
CRF Binder

Study
Progress

Data
Management

Site
Management

EFIC

Project
Setup

CC Form

CC Site Activity Summary

CC Closed Ended
Summary

CC Open Ended Coding

CC Question List

PD Form

PD Site Activity Summary

PD Closed Ended
Summary

User
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Community Consultation Form



List: CC Form

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#	Hub	Site	Name of Event	City	Start date of event	Type of event	Date First Entered	Last Updated	Locked
1	DHSU	Oregon Health & Science University Hospital, Portland, OR	Mary's Woods Health Fair Booth	Lake Oswego	24-Apr-2015	A Booth/table (where surveys were completed)	05-May-2015 1:48PM	07-Aug-2015	Yes
2	HFHS	Henry Ford Hospital, Detroit, MI	Brain Injury Association Meeting	Detroit, MI	18-Mar-2015	A presentation at a regular meeting with an existing group	05-May-2015 2:10PM	05-May-2015	No
3	Texas	Memorial Hermann Texas Medical Center, Houston, TX	University of Houston Honors College Medicine and Society Class	Houston	25-Mar-2015	A presentation at a regular meeting with an existing group	05-May-2015 3:37PM	28-Jul-2015	Yes
4	Emory	Applies to more than one site	Graduate Student Psychopharmacology Topic Discussion	Atlanta	24-Mar-2015	A presentation at a regular meeting with an existing group	06-May-2015 9:49AM	19-May-2015	No
5	PECARN	Children's National Medical Center, Washington, DC	Mary's Center Community Clinic	Washington, DC	21-Apr-2015	A presentation at a regular meeting with an existing group	07-May-2015 10:28AM	27-May-2015	No
6	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Positive Interaction Program for Deaf and Hard of Hearing	Houston	07-Apr-2015	A presentation at a regular meeting with an existing group	07-May-2015 10:50AM	28-Jul-2015	Yes
7	PECARN	Children's National Medical Center, Washington, DC	Brain Health Fair	Washington, DC	18-Apr-2015	A Booth/table (where surveys were completed)	07-May-2015 1:53PM	21-May-2015	No
8	PECARN	Nationwide Children's Hospital, Columbus, OH	Family Advisory Council Research Subcommittee	Columbus	30-Mar-2015	A focus group (moderated, small group sessions)	07-May-2015 2:10PM	29-May-2015	No
9	PECARN	Nationwide Children's Hospital, Columbus, OH	Central Ohio Pediatric Society	Columbus	15-Apr-2015	A convened mtg. with a targeted audience (invitation and rsvp collected)	07-May-2015 2:17PM	29-May-2015	Yes
10	PECARN	Children's National Medical Center, Washington, DC	Community Consultation in Hospital Cafeteria	Washington, DC	08-May-2015	A Booth/table (where surveys were completed)	11-May-2015 5:46PM	11-May-2015	No
11	UCSF	Applies to more than one site	SF Police Department Bayview Station Monthly Captain's Community Meeting	San Francisco	28-Apr-2015	A presentation at a regular meeting with an existing group	11-May-2015 6:53PM	06-Aug-2015	Yes
12	Mass General	Massachusetts General Hospital, Boston, MA	South Boston Neighborhood Advisory Committee Meeting	South Boston	01-Apr-2015	A presentation at a regular meeting with an existing group	12-May-2015 11:42AM	11-Aug-2015	Yes
13	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Rotary Club of the Galleria	Houston	23-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 3:37PM	28-Jul-2015	Yes
14	Texas	Memorial Hermann Texas Medical Center, Houston, TX	UT Houston School of Nursing 09:00 lecture class	Houston	27-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 3:50PM	28-Jul-2015	Yes
15	Texas	Memorial Hermann Texas Medical Center, Houston, TX	UT Health Research Coordinator Forum	Houston	24-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 4:14PM	28-Jul-2015	Yes
16	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Emergency Medicine Resident Conference	Houston	30-Apr-2015	A presentation at a regular meeting with an existing group	13-May-2015 4:20PM	28-Jul-2015	Yes
17	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Positive Interaction Program - Mykawa	Houston	09-Apr-2015	A presentation at a regular meeting with an existing group	13-May-2015 4:27PM	28-Jul-2015	Yes
18	Texas	Memorial Hermann Texas Medical Center, Houston, TX	North Montrose Civic Association	Houston	11-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 4:54PM	28-Jul-2015	Yes
19	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Rotary Club of the Sharpstown	Houston	17-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 4:54PM	28-Jul-2015	Yes
20	Texas	Memorial Hermann Texas Medical Center, Houston, TX	HPD Positive interaction Program - Kingwood	Houston	17-Mar-2015	A presentation at a regular meeting with an existing group	13-May-2015 6:20PM	28-Jul-2015	Yes

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Community Consultation Form & Points of Clarification

WebDCU™ for ESETT

https://webdcu.musc.edu/net/EditRecord2.asp?theFormID=702&theRecordID=0

Apps WebDCU™ Connect Pro Meetin... DCU Meeting Rem... UMCU craigslist ann arbor 2011PayFile - Acco... MyUofMHealth Injection.videos MapQuest Home | Active U... NETT FDA - Guidance WorkConnections - ... Google docs Yahoo! Other bookmarks Deneil HARNEY KOLK Sign Out

Edit: CC Form

No.	Item Description	Data Value
a	Hub/Institution	Please Select
b	Spoke/Site Spoke (if needed by the Hub)	No Option Provided
c	Name of Event (Should be specific & unique)	<input type="text"/>
d	Price to use this method (\$)	<input type="text"/> <small>do not include study/learn time or manpower hours</small>
e	City	<input type="text"/> (25 char.)
1	Start date of event	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy) Complete
2	Stop date of event	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy) Complete
3	Type of event	Please Select
4	If other, specify	<input type="text"/> (250 char.)
5	Lead Presenter	Please Select
6	Community type	<input type="radio"/> Geographical (general) community <input type="radio"/> Seizure related community <input type="radio"/> Both
7a	Intended Audience (Primary)	Please Select
7b	If Other, specify	<input type="text"/> (100 char.)
8a	What language was this event completed in?	<input type="radio"/> English <input type="radio"/> Spanish <input type="radio"/> Other
8b	If Other, specify	<input type="text"/> (75 char.)
9	IRB member(s) present	<input type="radio"/> No <input type="radio"/> Yes
10	Individual compensation provided	<input type="text"/>
11	Number of participants	<input type="text"/>
11a	Number of parents/guardians	<input type="text"/>
12	% Study supportive (% of audience/responders in support of the study)	<input type="text"/>
13	% EFIC supportive (% of audience/responders in support of EFIC for ESETT)	<input type="text"/>
14	Number of Opt-out Mechanisms requested	<input type="text"/>
Participant Demographic Data		
15	ESETT Instrument used	Please Select
17	Average age	<input type="text"/>
18	Males	<input type="text"/>
19	Females	<input type="text"/>
Ethnicity		
20	Hispanics / Latinos	<input type="text"/>
21	Non-Hispanics / Non-Latinos	<input type="text"/>

Make name unique and please no acronyms. Examples:

UK vs Hartford basketball game
Minnesota State Fair

Row 12: Can use % strongly agree and agree to survey Q,2

Row 13: Can use % strongly agree and agree to survey Q,3

of people that attended (may be larger than # that completed a survey).

CC Form – Points of Clarification cont.

WebDCU™ for ESETT

https://webdcu.musc.edu/nett/EditRecord2.asp?theFormID=702&theRecordID=0

3/7/2011 10:00 AM

If other schooling, specify (300 char)

Yearly household income

38 Was this information collected? No Yes

39 <= \$25,000

40 \$25,001 - \$50,000

41 \$50,001 - \$75,000

42 > \$75,000

Religion

43 Was this information collected? No Yes

44 Christian

45 Non-Christian

Have you or anyone you know ever experienced a seizure?

46 Me

47 My child

48 member or loved one

49 Someone else

50 No

Click in the white box to show the menu of drop down closed ended questions.

Closed-ended Section

51 **Closed-ended directions:** Select the closed ended questions captured for this CC event from the drop down box in column A2. If you used a closed-ended question not listed, email Deneil Harney at: dkoh@umich.edu with the question you need added.

No.	A2. Question	B. Strongly Agree or True or Yes	C. Agree	D. Neutral	E. Disagree	F. Strongly Disagree or False or No
51-1	1 ESETT is an important study to do. 2 If you developed a seizure that would not stop, you would be okay with being included in ESETT without giving your consent ahead of time. 3 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. 4 Do you think that ESETT researchers will seriously consider what community members like you have to say about this study before starting it? 5 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 ESETT study? 6. Would you like to tell doctors that you do not want to participate in ESETT? 6(alt.). Would you prefer not to participate in this study?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Open-e

52

No. **B. Comment Type**

52-1

Add New Row

f PDF (Attach published source here)

g Notes (500 char)

h Date First Entered (to be assigned by the system)

PDF: No file chosen

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CC Form – Points of Clarification cont.

WebDCU™ for ESETT Cu. x

https://webdcu.musc.edu/nett/EditRecord2.asp?theFormID=702&theRecordID=0

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37B If other schooling, specify _____ (300 char.)

Yearly household income

38 Was this information collected? No Yes

39 <= \$25,000

40 \$25,001 - \$50,000

41 \$50,001 - \$75,000

42 > \$75,000

Religion

43 Was this information collected? No Yes

44 Christian

45 Non-Christian

Have you or anyone you know ever experienced a seizure?

46 Me

47 My child

48 Another family member or loved one

49 Someone else

50 No

Closed-ended Section

51 **Closed-ended directions:** Select the closed ended questions captured for this CC event from the drop down box in column A2. If you used a closed-ended question not listed, email Deneil Harney at: dhk@umich.edu with the question you need added.

No.	A2. Question	B. Strongly Agree or True or Yes	C. Agree	D. Neutral	E. Disagree	F. Strongly Disagree or False or No
51-1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Add New Row

Open-ended Section

52 **Directions:** Put each unique statement on its own line.

No.	A. Open-ended comment (250 char.)	B. Comment Type
52-1	<input type="text"/>	<input type="text"/> <ul style="list-style-type: none"> Information still needed about ESETT Positive Comments about ESETT Concerns Other

Add New Row

f PDF (Attach published source here)

g Notes (500 char.)

h Date First Entered (to be assigned by the system)

PDF: No file chosen

A source file is optional if something extra was created.

Assign a comment type code to each statement.

Information still needed... is used for open ended comments to survey Q. 6.

You do not need to capture comments like, "nice presentation" or



Help

Enrolled 23% (23 / 100) of Projected Subjects

Subject
CRF Binder

Study
Progress

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Public Disclosure Form



List: PD Form

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#	Hub	Site	City	Phase of trial locally during this PD event	Title of event	Date of event	Method	PDF	First Entered On	Last Update On	Locked
1	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Houston	Before open enrollment	La Voz de Houston	22-Mar-2015	Newspaper	F1010.pdf	05-May-2015 2:12PM	05-May-2015	No
2	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Houston	Before open enrollment	Houston Press newspaper ad	19-Mar-2015	Newspaper	F1011.pdf	05-May-2015 2:40PM	05-May-2015	No
3	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Houston	Before open enrollment	Epilepsy Foundation Texas Tweet	13-Mar-2015	Social Media	F1013.pdf	07-May-2015 11:20AM	07-May-2015	No
4	Texas	Memorial Hermann Texas Medical Center, Houston, TX	Houston	Before open enrollment	Epilepsy Foundation of Texas - Facebook	13-Mar-2015	Social Media	F1014.pdf	07-May-2015 11:23AM	07-May-2015	No
5	PECARN	Children's National Medical Center, Washington, DC	Washington, DC	Before open enrollment	Children's National Twitter Post	27-Apr-2015	Social Media	F1015.pdf	07-May-2015 3:37PM	07-May-2015	No
6	PECARN	Children's National Medical Center, Washington, DC	Washington, DC	Before open enrollment	Children's National YouTube Video	27-Apr-2015	Social Media	F1016.pdf	07-May-2015 3:47PM	07-May-2015	No
7	Mass General	Massachusetts General Hospital, Boston, MA	Boston, MA	Ongoing (before-after)	Boston Public Library: West End Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1019.pdf	13-May-2015 5:15PM	13-May-2015	No
8	Mass General	Massachusetts General Hospital, Boston, MA	Boston, MA	Ongoing (before-after)	Boston Public Library: North End Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1020.pdf	13-May-2015 5:19PM	13-May-2015	No
9	Mass General	Massachusetts General Hospital, Boston, MA	Boston, MA	Ongoing (before-after)	Boston Public Library: South End Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1021.pdf	13-May-2015 5:21PM	13-May-2015	No
10	Mass General	Massachusetts General Hospital, Boston, MA	Roxbury, MA	Ongoing (before-after)	Boston Public Library: Dudley Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1022.pdf	13-May-2015 5:24PM	13-May-2015	No
11	Mass General	Massachusetts General Hospital, Boston, MA	Roxbury, MA	Ongoing (before-after)	Boston Public Library: Parker Hill Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1023.pdf	13-May-2015 5:26PM	13-May-2015	No
12	Mass General	Massachusetts General Hospital, Boston, MA	Jamaica Plain, MA	Ongoing (before-after)	Boston Public Library: Connolly Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1024.pdf	13-May-2015 5:28PM	13-May-2015	No
13	Mass General	Massachusetts General Hospital, Boston, MA	Roxbury, MA	Ongoing (before-after)	Boston Public Library: Egleston Square Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1025.pdf	13-May-2015 5:32PM	13-May-2015	No
14	PECARN	Children's National Medical Center, Washington, DC	Washington, DC	Before open enrollment	ESETT on Emergency Medicine Hospital Website	27-Apr-2015	Website	F1053.pdf	14-May-2015 3:41PM	19-May-2015	No
15	PECARN	Children's National Medical Center, Washington, DC	Washington, DC	Before open enrollment	ESETT on Epilepsy Hospital Website	27-Apr-2015	Website	F1052.pdf	14-May-2015 3:42PM	19-May-2015	No
16	PECARN	Children's National Medical Center, Washington, DC	Washington, DC	Before open enrollment	ESETT post on Children's National Facebook Account	27-Apr-2015	Social Media	F1051.pdf	14-May-2015 3:54PM	19-May-2015	No
17	PECARN	Children's Medical Center UTSW, Dallas, TX	Dallas	Before open enrollment	UTSW United to Serve Health Fair	18-Apr-2015	Information booth	F1028.pdf	15-May-2015 9:58AM	27-Aug-2015	No
18	Mass General	Massachusetts General Hospital, Boston, MA	Jamaica Plain, MA	Ongoing (before-after)	Boston Public Library: Jamaica Plain Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1030.pdf	15-May-2015 1:26PM	15-May-2015	No
19	Mass General	Massachusetts General Hospital, Boston, MA	Malden, MA	Ongoing (before-after)	Malden YMCA	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1031.pdf	15-May-2015 1:28PM	15-May-2015	No
20	Mass General	Massachusetts General Hospital, Boston, MA	Dorchester, MA	Ongoing (before-after)	Boston Public Library: Uphams Corner Branch	01-Apr-2015	Brochure/Poster/Flyer Distribution	F1032.pdf	15-May-2015 1:30PM	15-May-2015	No

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Public Disclosure Form – Points of Clarification

No.	Item Description	Data Value
1	Hub/Institution	Please Select
2	Spoke/Site (if needed by the Hub)	No Option Provided
2a	City	<input type="text"/>
3	Phase of trial locally during this PD event	<input type="radio"/> Before open enrollment <input type="radio"/> During enrollment period <input type="radio"/> After close of enrollment <input type="radio"/> Ongoing (before-after) <input type="radio"/> After results published
4	Title of event Title of event (Specify exact source)	<input type="text"/>
5	Date of event	<input type="text"/> (dd-mm-yyyy) Complete
6	Method	Please Select
7	If Other, specify	<input type="text"/> (50 char.)
8	Price to use this method (\$)	<input type="text"/> do not include study team time or manpower hours
9	Community Category	<input type="radio"/> Geographical (general) community <input type="radio"/> Seizure related community
10	Language	<input type="radio"/> English <input type="radio"/> Spanish <input type="radio"/> Other
11	If Other, specify	<input type="text"/> (50 char.)
12	Primary intended audience	Please Select
13	If Other, specify	<input type="text"/> (100 char.)
14	Number of people reached category	<input type="radio"/> Actual <input type="radio"/> Estimate <input type="radio"/> Unknown
15	Number of people reached	<input type="text"/>
16	Time Zone (when applicable)	Please Select
17	Time of event	<input type="text"/> Complete Time (24hr)
18	Duration (when applicable)	<input type="text"/> 30 sec, 5 min, 1 hr, etc (25 char.)
19	Run time (when applicable)	<input type="text"/> 1 day, 2 wks., ongoing, etc (25 char.)
20	Was feedback received?	<input type="radio"/> No <input type="radio"/> Yes
20a	If Q20 yes, specify:	<input type="text"/> (250 char.)
21	What mechanisms requested in response to this event	<input type="text"/> Leave blank if unknown
22	Web link to source event	<input type="text"/> (50 char.)
23	PDF (Attach published source here)	<input type="text"/>
24	Notes	<input type="text"/> (250 char.)
25	First Entered On	(to be assigned by the system)

PDF: No file chosen

The two possible choices available before enrollment. An example of Ongoing would be a website.

Be specific, no acronyms.
 Examples:
 Univ. of Michigan Facebook page
 Tacoma News Tribune article

A PDF source is very important. Please upload the actual newspaper, newsletter, etc., article, screen shot of website, etc.



Overview

Number of Hubs reporting:	30
Number of activity reports:	201
Number of participants:	32,638

Types of community involved

Percent geographic community:	56%
Percent condition-oriented community:	23%
Percent both types of community	21%

Type of consultation activities

Existing Group Meeting	36%
Self-Administered / In-Person Interview	27%
Booth Event	19%
Focus Group	8%
Convened Meeting (by invitation)	3%
Other	3%
Town Hall	1%
Internet Survey	1%
Phone Survey	1%

Participant Demographics

Age (average) 38 years

Female 64%
Male 36%

Race

White 67%
Black/African American 19%
Asian 5%
Native Hawaiian or Pacific Islander 1%
American Indian or Alaska Native 2%
More than one race 2%
Other race 5%

Ethnicity

Hispanic/latino 15%
Non-hispanic 85%

Overview (continued)

Intended event audience		intended audience versus community type (number of events)	
		geographic	condition-oriented
General	42%	79	28
Medical professionals	19%	2	6
Parents	16%	1	14
High risk specific	14%	9	20
Ethnic/racial community	2%	32	0
Age specific	1%	4	0
Formal community leader	1%	19	1
Civic group/informal leaders	0%	2	0

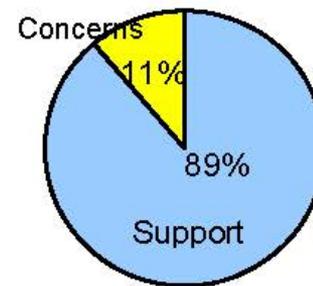
totals greater than 100% because some events included more than one intended audience or community type

Detail on types of community consultation activities

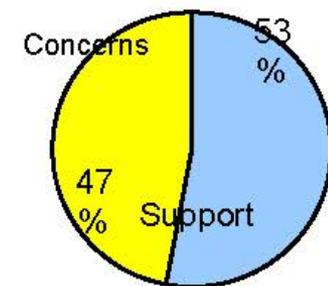
	<u>no. of events</u>	<u>no. of participants</u>
Existing Group Meeting	72	1,360
Self-Administered / In-Person Interview	54	1,696
Booth Event	39	21,777
Focus Group	17	179
Convened Meeting (by invitation)	7	84
Internet Survey	2	59
Town Hall	2	31
Phone Survey	2	500
Other	6	6,952

Feedback Summary

# of individual survey respondents	3,248
Total # of closed ended responses	19,634
Total # of open ended comments	1,343



Closed Ended Responses
Expressing Opinion
n= 18008



Open Ended Comments
Expressing Opinion
n= 525

CC Closed-ended Questions

Questions (in descending order by the number of respondents)	Yes or Strongly Agree	Agree	Neutral	Disagree	No or Strongly Disagree	Number of Respondents
ESETT is an important study to do.	57% 1848	36% 1183	6% 184	1% 20	0% 13	# 3248
If you developed a seizure that would not stop, you would be okay with being included in ESETT without giving your consent ahead of time.	44% 1437	36% 1162	12% 387	5% 172	3% 84	# 3242
If you are/were a parent, and your child developed a seizure that would not stop, would you be okay with him/her being included in ESETT without giving your consent ahead of time.	42% 1367	33% 1075	13% 432	8% 258	3% 107	# 3239
Do you think that ESETT researchers will seriously consider what community members like you have to say about this study before starting it?	78% 2148	0% 3	17% 475	0% 7	5% 130	# 2763
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 ESETT study?	89% 2545	0% 8	0% 3	0% 9	11% 324	# 2889
Would you like to tell doctors that you do not want to participate in ESETT?	15% 416	1% 17	1% 29	1% 40	81% 2194	* 2696
If you experienced a seizure that would not stop, would you be willing to be a part of this study without first giving your consent?	43% 220	0% 0	7% 36	0% 0	50% 257	# 513
Let's say your child had ongoing seizures that would not stop after being treated with the standard treatment. Would you be willing for your child to be included in this research even if it was not possible for you to provide consent ahead of time?	59% 100	0% 0	3% 5	0% 0	38% 64	# 169
Let's say you were the parent of a child between 2 and 18, and your child had ongoing seizures that would not stop after being treated with the standard treatment. Would you be willing for your child to be included in this research even if it was not possible for you to provide consent ahead of time?	59% 195	0% 0	8% 25	0% 0	33% 109	# 329
Are you in favor or not in favor of this study being conducted in your community?	83% 432	0% 0	10% 50	0% 0	8% 40	# 522
Would you prefer not to participate in this study?	13% 3	0% 0	0% 0	0% 0	86% 21	* 24

Enrollees' and Surrogates' attitudes toward enrollment & awareness survey

- Was incorporated into the ESETT Protocol
 - To capture quantitatively meaningful data on the views of all enrolled subjects within an EFIC study.
- Created in collaboration with the HSP-WG to be:
 - Brief
 - Easily administered verbally or in paper and pencil form
 - Completed following a consent decision to continue participation in ESETT
 - Including by subjects who refuse ongoing participation in ESETT
- It should be submitted for IRB approval along with consent docs.

Study ID _____

3a. Had you heard of the ESETT study before you were enrolled?
___ Yes
___ No

(If yes) 3b. How had you heard about this study?

4. When researchers do a study where people have to be included before being asked for permission, researchers have to talk to community members to get their thoughts and opinions about the study before it can be approved and started. This is in addition to having the study reviewed by the medical research review board that reviews all research studies.

a. In the ESETT study that you were included in, which groups of people do you think researchers should have talked to in order to get their thoughts about the study before the study started?

___ Members of the general public
___ Patients who have had seizures

Study ID _____

We think that it is important to understand patients' thoughts about research studies. This is especially important in the ESETT study that you were a part of. At the time you were included in this study, you were having a seizure so we were not able to talk to you about the study before including you. Now, we are asking everyone who was included in the ESETT study to answer a few questions about the study. You do not have to answer these questions, but we value any thoughts that you have about this study.

1. On a scale of 1 to 5 with 1 being strongly agree and 5 being strongly disagree, how do the following statements apply to you?

a. I am glad that I was included in the ESETT research study.

Strongly agree 1	2	3	4	Strongly disagree 5
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b. What is the major reason you chose this answer?

c. I think that it was ok for researchers to include me in the ESETT research study when I was having the seizure.

Strongly agree 1	2	3	4	Strongly disagree 5
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d. I think that it was ok to include me without asking for permission first.

Strongly agree 1	2	3	4	Strongly disagree 5
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2. Since you could not be asked about whether you wanted to be included in the ESETT study at the time you were having a seizure, you were told about it later and asked for permission to continue being part of the study. Thinking about when you were told about the study and asked whether you wanted to stay in it, can you tell me, on a scale of 1 to 5, how much you agree with the following statement?

a. I was told about the ESETT study at the appropriate time.

Strongly agree 1	2	3	4	Strongly disagree 5
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b. The research team treated me respectfully by asking for my permission to continue in the ESETT study.

Strongly agree 1	2	3	4	Strongly disagree 5
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c. Is there anything you would change about how you were told about the ESETT study or how we asked you for permission to continue in it?

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Who Should Complete the Survey:

- Adult enrollment
 - Subjects should be approached to complete the survey if capable
 - An LAR can complete the survey as well
- Peds enrollment
 - An LAR or Surrogate survey is all that is required
 - If a Peds subject would like complete the survey they may, but it is not required
- Spanish translation
 - Sites that have consents forms for ESETT translated into Spanish should also have IRB approval to use the attitudes surveys available in Spanish

Deneil Harney
(734) 232-2132
dkolk@med.umich.edu

