







Group#	Session/Week	x: Participa	nt ID#				
	Parent Weekly Questionnaire						
Please comp	olete the following g	uestions before th	e start of this o	group:			
1. Did you or	your child practice a	M3 skill since our la	ast session?				
□ Yes — — □ No	<b>—</b>						
a)	If yes, about how m	any times did you o	r your child prac	tice a M3 skill?			
	You: □ 1-3 □ 4-6 □ 7-10 □ 10+		□ 1-3 □ 4-6	Child Together			
b)	How many times did	d you and your child	practice a brea	thing break this week?			
c)	What situation led u  ☐ To practice ☐ other	Due to frustration		nger			
d)	Did you/your child fi You: Yes □ No □	=	Your Child:	Yes □ No □			
► 2. If no, wha	at kept you from prac	ticing M3 skills this	week?				

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# Parent Weekly Questionnaire

3) While practicing any of the M3 skills this past week, did you experience any of the following events:
a) Physical discomfort (aches, pains etc.)
□ No □ Yes, please explain:
b) Emotional discomfort or distress.
□ No □ Yes, please explain:
c) An increase in problems in relationships with others (e.g. child(ren), partner, co-worker)  □ No □ Yes, please explain:
4) While practicing any of the M3 skills this past week, did your child experience any unwanted negative events
□ No □ Yes, please explain:
5) In the past 7 days, how many seizures did your child have?
6) In the past 7 days, how many seizure-free days did your child have? (# seizure-free days)

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Parent	weekiy	/ Questi	onnaire

	Group#	_ Session/Week:	_ Participant ID#
	Please complete	the following questions	AFTER the group:
1.	What information/s	skills discussed today do	you think will be helpful for you as a parent?
	Why?		
2.	Were their certain less time on?	parts of our session toda	y that you felt we should have spent more time, or
3.	Were there any pa difficult concept).	rts of the session that yo	u found confusing? Why? (E.g., not enough time,
4.	Additional commer	nts/feedback?	

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### **Parent Pre Assessment**

ID Code:	Date:
	(DD-MMM-YYYY)

Based on the last 8 weeks, please answer the following statements by circling the response that best fits your opinion. There are no right or wrong answers. For example:

I eat bread	Never	Sometimes	Often	Regularly
I practice mindfulness.	Never	Sometimes	Often	Regularly
2. My child and I practice mindfulness together.	Never	Sometimes	Often	Regularly
<ol> <li>I think about the brain and how it connects to our emotions and behaviours when supporting my child.</li> </ol>	Never	Sometimes	Often	Regularly
<ol> <li>I am confident in my ability to help my child calm down when she/he is upset.</li> </ol>	Never	Sometimes	Often	Regularly
<ol><li>I use calm down tools in helping my child calm down when she/he is are upset.</li></ol>	Never	Sometimes	Often	Regularly
<ol><li>I am able to manage my own emotions when supporting my child's needs.</li></ol>	Never	Sometimes	Often	Regularly
7. I can recall and reflect on happy experiences between myself and my child	Never	Sometimes	Often	Regularly
8. I am able to be in the moment with my child when parenting with limited distractions.	Never	Sometimes	Often	Regularly
9. I am able to recognize in my body when I am feeling stressed.	Never	Sometimes	Often	Regularly
<ol> <li>I am able to look at my parenting from the perspective of who my child is and why she/he is doing what they are doing.</li> </ol>	Never	Sometimes	Often	Regularly
11. I feel confident in my ability to be firm but kind when supporting my child.	Never	Sometimes	Often	Regularly









### **Parent Post Assessment**

ID Code:	Date:
	(DD-MMM-YYYY)

Based on the last 8 weeks, please answer the following statements by circling the response that best fits your opinion. There are no right or wrong answers. For example:

16	eat bread	Never	Sometimes	Often	Regularly
1.	I practice mindfulness.	Never	Sometimes	Often	Regularly
2.	My child and I practice mindfulness together.	Never	Sometimes	Often	Regularly
3.	I think about the brain and how it connects to our emotions and behaviours when supporting my child.	Never	Sometimes	Often	Regularly
4.	I am confident in my ability to help my child calm down when she/he is upset.	Never	Sometimes	Often	Regularly
5.	I use calm down tools in helping my child calm down when she/he is are upset.	Never	Sometimes	Often	Regularly
6.	I am able to manage my own emotions when supporting my child's needs.	Never	Sometimes	Often	Regularly
7.	I can recall and reflect on happy experiences between myself and my child	Never	Sometimes	Often	Regularly
8.	I am able to be in the moment with my child when parenting with limited distractions.	Never	Sometimes	Often	Regularly
9.	I am able to recognize in my body when I am feeling stressed.	Never	Sometimes	Often	Regularly
10	. I am able to look at my parenting from the perspective of who my child is and why she/he is doing what they are doing.	Never	Sometimes	Often	Regularly
11	. I feel confident in my ability to be firm but kind when supporting my child.	Never	Sometimes	Often	Regularly

### Parent Post Assessment

Based on the last 8 weeks, please answer the following statements by selecting the response that best fits your opinion. There are no right or wrong answers.

	Ve Dissat	. I Diccatiction		Neutral S		Satisfied	Very Satisfied	
12. How would you rate your overall satisfaction with the M3 program?								
		Stron Disag		Disagree	Neithe agree no disagre	or	Agree	Strongly Agree
13. I found this program informative			]					
14. I found this program to be helpful			]					
15. I found the online program easy to us	se		]					
16. I was happy to use the computer to access the M3 intervention								
17. The online format made it easier to a each session	ttend		]					
18. I was happy with the amount of interaction and engagement in the progr	am		]					
19. I would recommend this on-line prog to a friend	ram		]					
20. What did you most like about the onlin	ne prog	ram?						
21. What did you least like about the onlin	e progr	ram?						









# **Child Pre and Post Assessment**

Date:					
ID Code:					
1. I know ho	=	n works when I am	Yes	I don't know	No
	<u>· · · · · · · · · · · · · · · · · · · </u>				
2. I know wł	nat a breat	hing break is.			
	<u> </u>				
3. I use brea	athing brea	ıks to calm my big feeli	ngs.		
4. I have lot	s of great i	deas to help me when	I have a p	oroblem.	
	<u></u>				
5. I know h	ow to be ki	nd to others.			
6. Mindfulne	ess is				

# M3 Adherence Checklist. Session # \_\_\_\_\_

Facilitator Names: _						
Date: (day/month/year) Group Number:						
Person(s) filling out this form :   □ Parent Group □ Child Group						
# of Participants:						
Did you complete e	ach activity below?					
Task 1:	Task 2:	Task 3:	Task 4:	Task 5:	Task 6:	Task 7:
[Task name goes	[Task name goes	[Task name goes	[Task name goes	[Task name goes	[Task name goes	[Task name goes
here]	here]	here]	here]	here]	here]	here]
☐ Yes Completely	☐ Yes Completely	☐ Yes Completely	☐ Yes Completely	☐ Yes Completely	☐ Yes Completely	☐ Yes Completely
☐ Yes with changes	☐ Yes with changes	☐ Yes with changes	☐ Yes with changes	☐ Yes with changes	☐ Yes with changes	☐ Yes with changes
□ No	□ No	□ No	□ No	□ No	□ No	□ No
If you made change:	s, please describe the	here, or if you did no	t complete an activity	, please describe why	here.	

\_\_\_\_\_Total # of activities competed out of 7
\_\_\_\_\_Total # of activities not completed

How would you rate your overall satisfaction with:

	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied	
Today's on-line session overall						
The interaction and engagement of the participants						
The online format of the session						
Ease of use of delivering the intervention online						
Which activities listed above did the participants seem well engaged in and why?						
Which activities did the participants no	ot seem enga	ged in and w	hy?			

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# M3-E RCT

# **QUALITY OF IMPLEMENTATION**

□ Parent Group	☐ Child Group			
Group Number:		Date: _		
			(dd/mr	m/yyyy)
Session #:		# of Part	cicipants:	
Your name (observ	er):			
Instructions				
	ions assess the ov	verall quality of the M3 s	session and d	elivery of the
		e form after observing the		•
	•	become familiar with the		•
	<b>=</b>	for example, each time a	-	<u> </u>
•		e appropriate rating. Use	-	-
•		E: this questionnaire will	•	•
responses will not se	en by the progra	m facilitators.		-
1. How prepared w	ere the facilitate			
1	2	3 Samarrhat	4	5
Not Prepared	2	Somewhat Prepared	4	Very Prepared
with activities		, facilitators did not arrive on ot fully prepared to start sess		
	and set up for activ	ities, facilitators early to on-i	line session, fac	ilitators very familiar with
2. In general, how o	clear were the p	rogram facilitators' exp	olanations of	activities?
1	2	3	4	5
Not clear	<b>2</b>	Somewhat clear	7	Very clear

- 1- Most participants did not understand instructions and could not proceed, many questions asked
- 3- About half of the group understood, while the other half asked questions for clarification
- 5-90-100% of the participants began and completed the activity/discussion with no hesitation and no questions

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# 3. To what extent did the facilitators keep track of time during the session and activities?

1 Not on time 2 Some loss of time 4 Well on Time

- 1- Facilitator did not have time to complete the material (particularly at the end of the session), regularly allowed discussions to drag on (e.g., participants seem bored or began discussing non-related issues in small groups)
- 3- Missed a few points, sometimes allowed discussions to drag on
- 5- Completed all content of the session, completed activities and discussions in a timely manner (using the suggested time limitations in the program manual, if available)

# 4. To what extent did the presentation of materials seem rushed or hurried?

1 Very rushed 2 Somewhat rushed 5 Not rushed

- 1- Facilitators didn't allow time for discussion, didn't have time for examples, told participants that they were in a hurry, body language suggested stress or hurry
- 3- Some deletion of discussion/activities, sometimes stated but does not explain material
- 5- Didn't rush participants or speech but still completed all the materials, appeared relaxed

# 5. To what extent did the participants appear to understand the material?

1 3 5
Little 2 Some 4 Good understanding understanding understanding

*Use your best judgment based on participant conversations and feedback. Roughly: 1 - Less than 25% seemed to understand; 3 - About half; 5 - 75-100% understood* 

### 6. How actively did the group members participate in discussions and activities?

1 3 5
Little 2 Some 4 Active
Participation participation participation

*Use your best judgment based on listening to the discussions and feedback. Roughly, 1 - Less than 25% participated; 3 - About half participated; 5 - 75-100% participated* 

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1 Poor	2	3 Average	4	5 Excellent
unfocused		uiet participants, did not mo		
ow well did fac	ilitators manage	e the use of technology	to present the	session materia
1 Poor	2	3 Average	4	5 Excellent
CONTRACTOR WILL IN		ing.5 - Screen sharing was s	Our or viver ourled	
rooms or the cha	t function was well n	nanaged and conducive to le	earning	,, we use of events
rooms or the cha	t function was well n	nanaged and conducive to le	earning	5 Excellent
rooms or the char ow well did the 1 Poor 1 – During active accomplishments 3 – Limited use of 5 – During active accomplishments	e facilitators supported to the supporte	port and encourage part and encourage part and encourage part and encourage part actively involved with particle of limited use of open-ended ons, used subjective or evaluate actively involved with particle active activ	earning  articipants.  4  cipants, did not sup questions uative language (I leticipant, supported)	5 Excellent port contributions o ike it, you're smart, contributions or
rooms or the char ow well did the 1 Poor 1 – During active accomplishments 3 – Limited use of 5 – During active accomplishments your project), free	e facilitators supple 2  ities, facilitators not a soft open-ended question ities, facilitators were swith specific and not equently used open-ended provided, rate the provided, rate the specific and provided, rate the provided, rate the specific and provided and provi	port and encourage part and encourage part and encourage part and encourage part actively involved with particle of limited use of open-ended ons, used subjective or evaluate actively involved with particle active activ	earning  articipants.  4  cipants, did not sup questions  native language (I leticipant, supported  an tell that you put o	5 Excellent  port contributions of ike it, you're smart, contributions or a lot of thought into
rooms or the char ow well did the 1 Poor 1 – During active accomplishments 3 – Limited use of 5 – During active accomplishments your project), free	e facilitators supple 2  ities, facilitators not a soft open-ended question ities, facilitators were swith specific and not equently used open-ended provided, rate the provided, rate the specific and provided, rate the provided, rate the specific and provided and provi	port and encourage per 3 Average actively involved with partice of open-ended ons, used subjective or evaluate actively involved with partice active a	earning  articipants.  4  cipants, did not sup questions  native language (I leticipant, supported  an tell that you put o	5 Excellent  port contributions of ike it, you're smart, contributions or a lot of thought into

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1 Poor	2	3 Average	4	5 Exceller
	-	, didn't summarize key mes on, provided key take away		
Level of enthusia	asm			
1 Poor	2	3 Average	4	5 Excellen
"burned out"		boring way, lacked persond		
Poise and confid	ence			
1 Poor	2	3 Average	4	5 Exceller
		ot have good eye contact erns, was well organized, no	ot nervous	
Rapport and con	nmunication wit	h participants		
1 Poor	2	3 Average	4	5 Exceller
1 – Didn't rememb		onnect" with participants, very friendly, used people	-	
5 - Got participant	nmunity and its need.	S		
5 - Got participant understand the con	essed questions/c			

5 - Answered questions of fact with information and questions of value with validation, if didn't know the answer was honest about it and directed them elsewhere

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# g) Provided a welcoming on-line atmosphere

1 Poor 2 3 4 5 Excellent

1-Did not greet participants, little to no eye contact, stiff instead of animated body language, negative tone of voice, hard to see on the screen (only see part of their face or body)

5 – Greeted all participant, made eye contact with participant when addressing them, smiled, showed open body language, easily seen on the screen, , used warm tone of voice, used respectful language

# h) Effectively transitioned from one activity to another

1 Poor 2 3 4 5 Excellent

5 – Used transitions to connect one activity to another, transitions were smooth and clear.

# i) Effectively managed the emotional climate

1 Poor 2 3 4 5 Excellent

#### 11. Rate the overall quality of the program session.

1 Poor 2 3 4 5 Excellent

Summary measure of all the preceding questions - assesses the extent of material covered and performance of the facilitator.

#### Excellent sessions look like:

- Participants were doing rather than talking about activities
- Non-judgmental responses to questions
- Answering questions of fact with information, questions of value with validation
- Good time management and well organized
- Adequate pacing—not too fast and did not drag
- Used effective checks for understanding.
- Supportive and encouraging towards participants.

### Poor sessions look like:

- Lecture-style presenting of content
- Reading the content from the notebook
- Stumbled along with the content and failing to make connections to what has been discussed previously or what participants are contributing.
- Uninvolved participants
- Got into power struggles with participants about the content.
- Judgmental responses
- Flat affect and boring style
- Unorganized and random
- Lost track of time

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<sup>1</sup> – Did not use transitions or transitions were unclear and confusing.

<sup>1 –</sup> Emotional climate was negative, negative behaviors were not mediated, comments with bias were not addressed

<sup>5 –</sup> Emotional climate was positive, respectful and fun; negative behaviors and biased comments were mediated, or there was no evidence of bias but rather a mutual respect and inclusion of others

12. Please note at least one major strength of the session and/or facilitators' delivery of the material.

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#### LETTER OF INFORMATION FOR PARENTS/GUARDIANS

Study Title: Making Mindfulness Matter in Children with Epilepsy (M3 Epilepsy)

Principal Investigator: Kathy Nixon Speechley, Ph.D.

[Contact Details]

Funder: Canadian Institutes of Health Research

#### 1. Invitation to Participate

As co-principal investigators, Dr. Kathy Nixon Speechley and Dr. Karen Bax are inviting you and your child who has epilepsy to participate in research about the health and mental health benefits of program that teaches mindful awareness and social-emotional skills because we know that epilepsy can negatively impact quality of life for children and their families.

#### 2. Why is this study being done?

The purpose of this study is to determine whether or not a live online group program called Making Mindfulness Matter can benefit children with epilepsy and their parents. Making Mindfulness Matter (M3) teaches mindful awareness and social-emotional skills in an online group setting to learn to pay better attention to our feelings, thoughts and behaviours in the moment so that we can better manage strong emotions, make positive choices, and feel less stress. There is very little research that describes how a program like this could support well-being for both children and parents.

The study aims to evaluate M3 as a family support and determine whether the M3 program has a positive effect on quality of life and well-being for children with epilepsy and their parents. This letter outlines the procedures for the study. If you agree to participate, you will be asked to sign the consent form.

#### 3. How long will you be in this study?

The M3 program is 8 weeks long, with a 1.5 hour online group session each week for parents and a 1-hour online group session for children. The group sizes are small (4 to 8 people), and children and parents will be in separate sessions and come together in a combined segment at the end of each child session. In addition to the M3 program, you will be asked to complete questionnaires two or three times: at the start of the study and at 8 weeks and, for half of you, 18 weeks later. Therefore, the total duration of the study will be 18 weeks. The questionnaires are estimated to take 90 minutes to complete.

#### 4. What will happen during the study?

If you decide to participate, you will be "randomized" to either begin the program right away or 10 or more weeks later (depending on when the next group session will be scheduled). Randomization means that you are put into a group by chance (like flipping a coin). You will have an about 50:50 chance of starting the program right away or 10 or more weeks later, there is no way to predict when you will begin the program. Neither you nor the researchers can choose if you will begin the program right away or 10 or more weeks later. Your epilepsy care will continue as usual throughout the entire course of the study.

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The study is designed for children aged 4 to 10 years who were diagnosed with epilepsy at least 6 months ago including those who are still having seizures as well as those who are seizure-free and their parent/guardian.

#### 5. What are the study procedures?

After consent, you will be asked to complete questionnaires at two time points: at the start of the study and 8 weeks afterwards. Those who begin the program right away, will complete an additional questionnaire18 weeks after the first. Most questions ask about your child and some questions are about you, as the parent/caregiver. There are also demographic questions about your household. Questions will ask about your child's experiences, current quality of life, stress, behavior and feelings. At the start of the study, your child's neurology clinician will complete a one-page questionnaire to provide the researchers with information about your child's epilepsy such as type and severity.

You will also be asked a few questions at each group session to gather additional feedback about the M3 program and your experience with mindfulness. Some examples include, "Did you or your child practice a mindful skill since our last session?" and "Were there any parts of the session you felt were confusing?

Just prior to starting the program and following the last session, your child will be asked to complete a "feeling face" questionnaire about topics discussed in the group such as how our brain works when we are upset and what is mindfulness. The questions will be read to the children by the researcher and the children will respond online with the face that best represents how they feel.

Both you and your child may choose to not answer any question you wish. None of the answers you or your child provide will contain any personal information (e.g., name) that could be used to identify you or your child. You will complete these online questionnaires at home. You will be provided with an individualized link to the questionnaire through email.

Regardless of when you begin the M3 program, your epilepsy care will continue as usual.

### 6. What are the possible risks of participating in this study?

The potential risks associated with participation in the present study are low. If you experience stress while participating in the study, you may find it beneficial to access this website describing strategies for handling stress: <a href="https://childdevelopmentinfo.com/family-living/stress/#.WJtAdG8rK70">https://childdevelopmentinfo.com/family-living/stress/#.WJtAdG8rK70</a>. During the M3 sessions, facilitators will be available to discuss strategies related to stress reduction, and you will be asked weekly whether you are experiencing any increase in stress as a result of the program. Referrals to other resources will be provided if needed.

While there is no guarantee, we will do our best to protect the privacy of all your information by using only a study number and not including your name on any questionnaires or forms that might allow you to be individually identified.

#### 7. What are the benefits?

A benefit of this study is that it provides an opportunity to experience the potential benefits that mindful awareness may have for you and your child's health and mental health (e.g., decreased feelings of stress, more focused attention in the moment, better management of strong emotions), although it is possible that you will not experience any direct benefits by participating.

#### 8. Is participation voluntary?

Participation is voluntary including speaking to the researchers and you may also withdraw your participation in the research study and/or your child's at any time without any negative consequences. If you decide to

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withdraw your own and/or child's participation from the study, you will have the choice of whether the information that was collected prior to you leaving can still be used in the study.

#### 9. How will information be kept confidential?

Your identity and that of your child will be kept confidential in any reports or presentations that result from the study. The responses from the questionnaires about you and your child will be put into a computer database called REDCap that is password protected and only accessible by study staff. REDCap servers follow hospital security guidelines and policies and all the web-based information transmission is encrypted. REDCap was developed specifically around privacy guidelines and is recommended to researchers by Privacy Offices and Institutional Review Boards of many organizations. Your name, telephone, address, e-mail and full date of birth will also be kept securely in REDCap and on a master list so we can contact you and administer the study. Any written information that identifies you/your child will be kept in a locked filing cabinet in the research office.

According to Lawson Health Research Institute policy, collected information will be kept for 15 years and then the computer file will be permanently deleted and the consent forms in the file will be shredded. Representatives of the University of Western Ontario Research Ethics Board or Lawson Health Research Institute may require access to your study-related records to monitor the conduct of the research.

#### 10. Are participants compensated for being in the study?

Should you choose to participate you will receive a \$25.00 gift card each time you are asked to complete the questionnaire at the start of the study and at 8 weeks. Those who are asked to complete a follow-up questionnaire will receive an additional \$25.00 gift card at 18 weeks.

#### 11. What are the rights of the participants?

You have the right to not answer individual questions about you and your child. You do not waive any legal rights by providing consent to participate.

### 12. Whom do participants contact for questions?

If you would like more information about this project, please contact Dr. Speechley by phone XXX-XXX-XXX or by email XXXXXXXXX. If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: https://apps.lhsc.on.ca/?q=forms/patient-relations-contact-form.

In a few days, a member of our research team will telephone you to answer any questions you may have about the study and find out whether you wish to participate. If you agree, you will be provided a link to consent on-line through REDCap.

Sincerely,	
Kathy Nixon Speechley, Ph.D.	Karen Bax, Ph.D., C. Psych.

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#### **ASSENT LETTER**

Study Title: Making Mindfulness Matter in Children with Epilepsy (M3 Epilepsy)

Principal Investigator: Kathy Nixon Speechley, Ph.D.

[contact details]

# 1. Why are you here?

Epilepsy can make life harder. You are being invited to be part of a study to see if there are ways that may make living with epilepsy easier.

# 2. Why are we doing this study?

The aim of the study is to see if a mindful awareness group program can help children with epilepsy and their parents feel better. Mindful awareness simply means noticing what is happening right now. The live online group program teaches things like being able to notice what is happening right now, learning to control big emotions and being positive.

# 3. What will happen to you?

If you want to be in the study, you will join the online child program for 8 weeks with other children. At another time, your Mom or Dad will join the online parent program. At the end of each session your Mom or Dad will come in your group and practice a mindful skill with you.

# 4. Will there be any tests?

No, there will not be any tests. There will be questions for your parents to answer about how you are doing. At the beginning of the class and 8 weeks later, we will ask you some questions on how you feel about what you learned. At the start of the study, your doctor will answer questions about your health.

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# 5. Do you have to be in the study?

You do not have to be in the study. No one will be mad at you if you do not want to do this. If you do not want to be in the study, tell the program leader or your parents. Even if you say yes, you can change your mind later.

# 6. What if you have questions?

You can ask questions at any time, now or later. You can ask your family or the program leader or contact Dr. Kathy Speechley.

### **Assent Form**

Study Title: Making Mindfulness Matter in Children with Epilepsy (M3 Epilepsy)

**Principal Investigator:** Kathy Nixon Speechley, Ph.D. [Contact Details]

Assent form was discussed and the child agreed to participate.	$\Box$ Yes	$\square$ No
Person obtaining assent		
Signature of person obtaining assent		_
Date assent was obtained		

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