Childhood Adenotonsillectomy Study Adverse Event

Site: _____

AE #	CTCAE Name Please use CTCAE code number	Event Name	Date of Onset	Grade	Relationship to Study Treatment	Action taken regarding Study Treatment	Treatment for event	Seriousness	Date of Resolution Enter date OR check box if AE is continuing	Was Event Serious?
				1.Mild 2.Moderate 3.Severe 4.Life threatening or disabling 5.Fatal	1.Unrelated 2.Possibly related 3.Probably 4.Definitely related	0.No action taken 1.Treatment interrupted 2.Treatment discontinued	0.No 1.Yes	See key below table		0.No 1.Yes Yes, if Serious- ness 3-8
			mm/dd/yyyy	record one	record one	record one	record one	record most appropriate	mm/dd/yyyy	
			//						//	
			//						//	
			//						//	
			//						//	
			//						//	
			//						//	

<u>Seriousness Key</u> 1.Resolved/ no follow-up needed 2.On-going/treatment continued 3.Hospitalization or prolongation of existing hospitalization

4.Resulted in persistent or significant disability/ incapacity 5.Congenital anomaly/ birth defect 6.Life threatening

7.Fatal 8.Other Important Medical Event/SAE

C H A T	Anthropometry	DMY STUDY Participant ID: Participant Initials: Site: Date:/ RC ID:
1.	Date of the current measurements:	
2.	. Time of the current measurements:	(24 Hour Clock)
3.	. What is the child's current standing height?	cm
4.	. What is the child's current weight?	kg
5.	. What is the child's current BMI?	
	*PI	ease note, after BMI is calculated by the DMS write the result in the shaded area $\!\!\!\!^\star$
	5a. What is the child's BMI z-score?	 ₉₉ Not required at this visit
		ease note, the BMI z-score be obtained from the following website: p://www.bcm.edu/cnrc/bodycomp/bmiz2.html *
	* Als	o note – the BMI z-score is only collected at the Baseline visit *

Body Measurements:

** Please note, AVERAGE totals for Neck, Waist, and Hip Circumference will be calculated by the DMS **

_		Measurement 1	Measurement 2	Measurement 3	Average
6.	Neck Circumference:	cm	cm	cm	
7.	Waist Circumference:	cm	cm	cm	·
8.	Hip Circumference:	cm	cm	cm	·

* Please note, after Neck, Waist, and Hip Circumferences are calculated by the DMS write the results in the shaded area *

CHILDHOOD ADENOTONSILLECTOMY STUDY	Participant ID:
Blood Pressure	Participant Initials:
Visit	Site:
	Date: / / /
	RC ID:

** Please note, AVERAGE Resting Blood Pressure will be calculated by the DMS **

1.	Resting	Blood Pressure 1:	/
	1a.	Time collected:	(24 Hour Clock)
2.	Resting	Blood Pressure 2:	/
	2a.	Time collected:	(24 Hour Clock)
3.	Resting	Blood Pressure 3:	/
	За.	Time collected:	(24 Hour Clock)
4.	Average	Blood Pressure:	** After Average Blood Pressure is calculated by the DMS, please write it in the shaded area **

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C H A T	CHILDHOOD ADENOTONSI BRIEF Visit	Participant Initials:	
1.	Was the form completed?	□₀ No □₁ Yes	
2.	Who completed this form?	\square_1 Biological Parent \square_2 Adoptive Parent \square_3 Step Parent \square_4 Foster Parent \square_5 Grandparent \square_{98} Other, please specify:	

Please provide the scores from the BRIEF questionnaire

	Scale / Index	Raw Score	T Score	Percentile
3.	Inhibit			
4.	Shift			
5.	Emotional Control			
6.	BRI			
7.	Initiate			
8.	Working Memory			
9.	Plan / Organize			
10.	Organization of Materials			
11.	Monitor			
12.	MI			
13.	GEC (BRI + MI)			
14.	What is the negativity score?	Acceptal	ble 2 Elevated	\Box_3 Highly Elevated
15.	What is the inconsistency score?	□₁ Acceptal	ble \square_2 Questionable	\Box_3 Inconsistent

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUD BRIEF Teacher's Form Visit	Y Participant ID: Participant Initials: Site: Date:/ NP ID:
1.	Was the Brief Teacher's Form completed and returned?	□₀ No □₁ Yes
2.	How well does the teacher know the child?	□ 1 Not Well □ 2 Moderately Well □ 3 Very Well
3.	How long has the teacher known the child?	Months

Please provide the scores from the BRIEF questionnaire

	Scale / Index	Rav	w Score	T Sco	ore	Percentile
4.	Inhibit					
5.	Shift					
6.	Emotional Control					
7.	BRI					
8.	Initiate					
9.	Working Memory					
10.	Plan / Organize					
11.	Organization of Materials					
12.	Monitor					
13.	MI					
14.	GEC (BRI + MI)					
15.	What is the negativity score?		□ ₁ Acceptat	ole 🛛 2 Ele	vated	\Box_3 Highly Elevated
16.	What is the inconsistency score?		1 Acceptat	ole 🗌 ₂ Qu	estionable	\square_3 Inconsistent

C H A T	CHILDHOOD ADENOTONSILLECTOM Child Behavior Checklist Visit	Y STUDY Participant ID: Participant Initials: Site: Date:// NP ID:
1.	Was the Checklist completed?	□ ₀ No □ ₁ Yes
2.	Who completed this form?	\square_1 Biological Parent \square_2 Adoptive Parent \square_3 Step Parent \square_4 Foster Parent \square_5 Grandparent \square_{98} Other, please specify:

Please provide the summary scores from the CBCL questionnaire.

		Total Score	T Score	Percentile
3.	Activities:			
4.	Social:			
5.	School:			
6.	Total Competence:			
7.	Anxious / Depressed:			
8.	Withdrawn / Depressed:			
9.	Somatic Complaints:			
10.	Social Problems:			
11.	Thought Problems:			
12.	Attention Problems:			
13.	Rule-Breaking Behavior:			
14.	Aggressive Behavior:			
15.	Internalizing Problems:			
16.	Externalizing Problems:			
17.	Total Problems:			
18.	Affective Problems:			
19.	Anxiety Problems:			
20.	Somatic Problems:			

CHILDHOOD ADENOTONSILLECTOMY STUDY Child Behavior Checklist Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / /
NP ID:

		Total Score	T Score	Percentile
21.	Attention Deficit / Hyperactivity Problems:			
22.	Oppositional Defiant Problems:			
23.	Conduct Problems:			

C H A T	CHILDHOOD ADENOTONSILLECTON Child Depression Inventory Age 7 and up Visit	
1.	Was this test performed?	□ ₀ No □ ₁ Yes
	1a. If NO, please provide a reason:	\square_1 Child is not of Age \square_2 Other, specify:
2.	Was any assistance given to the child during the administration of this test?	□ ₀ No □ ₁ Yes
3.	Did the child endorse a score of "3" on Item 9?	□₀No

\square_1 Yes

Please provide the Total Scores and T-Scores from the CDI

		Total Score	T-Score
4.	Total CDI Score:		
5.	Scale A: Negative Mood		
6.	Scale B: Interpersonal Problems		
7.	Scale C: Ineffectiveness		
8.	Scale D: Anhedonia		
9.	Scale E: Negative Self-Esteem		

C H A T	CHILDHOOD ADENOTONSILLECTON Child Demographic Informatio BASELINE [Parent / Guardian Completed]	on	Participant ID: Participant Initials: Site: Date: / / RC ID:
1.	What is your child's Date of Birth?	<u>m</u> m / <u>- </u> _	/ _Y _ _Y _ _Y _ _Y
	1a. What is your child's age?	Years	Months
2.	What is your child's gender?	□ ₁ Male	\square_2 Female
3.	What is your child's ethnicity?	\square_1 Hispanic \square_2 Not Hispa	
4.	What is your child's race?		
5.	What is your child's current or most recently completed grade in school?	Grade	nding
	5a. If your child is not attending, please provide a reason:		Vacation ome schooled ecify:

Participant ID:
Participant Initials:
Site:
Date: / /
NP ID:

Directions:

This form should be read to the child (ages 5 - 7), use the template attached to this CRF (also included in the MOP), which has the smiley face icons as reference for each of the three possible answers – Not at all, Sometimes, and A lot.

<u>Say to the child:</u> Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading each item below, gesture to the smiley face template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the smiley face icons.

1.	Physical Functioning (problems with):	Not at all	Sometimes	A lot
1a.	Is it hard for you to walk?			4
1b.	Is it hard for you to run?	0		4
1c.	Is it hard for you to play sports or exercise?			4
1d.	Is it hard for you to pick up big things?			4
1e.	Is it hard for you to take a bath or shower?	0		4
1f.	Is it hard for you to do chores (like pick up your toys)?			4
1g.	Do you have hurts or aches (Where)?			4
1h.	Do you ever feel too tired to play?			4

2.	Emotional Functioning (problems with):	Not at all	Sometimes	A lot
2a.	Do you feel scared?			\Box_4
2b.	Do you feel sad?			\Box_4
2c.	Do you feel mad?	 0	_ 2	4
2d.	Do you have trouble sleeping?			\Box_4
2e.	Do you worry about what will happen to you?	 0	_ 2	4

3.	Social Functioning (problems with):	Not at all	Sometimes	A lot
За.	Is it hard for you to get along with other kids?			4
3b.	Do other kids say they do not want to play with you?	0	_ 2	4
3c.	Do other kids tease you?			4
3d.	Can other kids do things that you cannot?		_ 2	4
3e.	Is it hard for you to keep up when you play with other kids?			\Box_4

4.	School Functioning (problems with):	Not at all	Sometimes	A lot
4a.	Is it hard for you to pay attention in school?			4
4b.	Do you forget things?			4
4c.	Is it hard to keep up with schoolwork?			4
4d.	Do you miss school because of not feeling good?			4
4e.	Do you miss school because you have to go to the doctor's or hospital?			4

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

How much of a problem is this for you?



CHILDHOOD ADENOTONSILLECTOMY STUDY PedsQL – Child Report (ages 8 – 12) Visit ____

Participant ID:	
Participant Initials:	
Site:	
Date: / / / /	
NP ID:	

<u>Directions</u>: The following is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by checking the box. There are no right or wrong answers. If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you...

1.	About My Health and Activities (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
1a.	It is hard for me to walk more than one block				\square_3	4
1b.	It is hard for me to run					4
1c.	It is hard for me to do sports activity or exercise					4
1d.	It is hard for me to lift something heavy					4
1e.	It is hard for me to take a bath or shower by myself				\square_3	
1f.	It is hard for me to do chores around the house					4
1g.	I hurt or ache					4
1h.	I have low energy		1		3	4

2.	About My Feelings (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
2a.	I feel afraid or scared			2	_ 3	
2b.	I feel sad or blue		1	 2	3	4
2c.	I feel angry				_ 3	
2d.	I have trouble sleeping		1	 2	3	4
2e.	I worry about what will happen to me				\square_3	

3.	How I Get Along With Others (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
За.	I have trouble getting along with other kids				\square_3	4
3b.	Other kids do not want to be my friend	Οο			\square_3	
3c.	Other kids tease me				\square_3	
3d.	I cannot do things that other kids my age can do			_ 2	3	4
3e.	It is hard to keep up when I play with other kids				\square_3	

4.	About School (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
4a.	It is hard to pay attention in class				\square_3	\Box_4
4b.	I forget things				\square_3	
4c.	I have trouble keeping up with my schoolwork				\square_3	
4d.	I miss school because of not feeling well					4
4e.	I miss school to go to the doctor or hospital					

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CHILDHOOD ADENOTONSILLECTOMY STUDY Concominant Medications

Participant ID: __ _ _ _ _ _ _ _ _ _ _ _ Participant Initials: __ _ _ _ Site: __ _

#	Drug Code	Medication Name	Start Dates	Stop Dates Check box if medication is continuing.	Total Daily Dose	Unit 1 = mg 7 = oz 2 = mcg 8 = drops 3 = tablets 9 = spray 4 = ml/cc 10 = units 5 = tsp 98 = Other 6 = tbsp 98	Frequency 1 = qd 2 = bid 3 = tid 4 = qid 5 = PRN 98 = Other	Route1 = Oral7 = Nasal2 = IV8 = Transdermal3 = IM9 = Inhalant4 = SC10 = Sublingual5 = Topical98 = Other6 = Rectal

Participant ID:
Participant Initials:
Site:
Date: / /
NP ID:

1. Was the questionnaire given to the parent / guardian?

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\Box_0	No
\Box_1	Yes

Please provide the summary scores from the Conners' questionnaire.

		Raw Score	T-Score
2.	Oppositional:		
3.	Cognitive Problems / Inattention:		
4.	Hyperactivity:		
5.	Anxious / Shy:		
6.	Perfectionism:		
7.	Social Problems:		
8.	Psychosomatic:		
9.	Conners' ADHD Index:		
10.	Conners' GI Restless – Impulsive:		
11.	Conners' GI Emotional Liability:		
12.	Conners' GI Total		
13.	DSM-IV Inattentive:		
14.	DSM-IV Hyperactive-Impulsive:		
15.	DSM-IV Total:		
16.	Inattentive Symptoms:		
17.	Hyperactive-Impulsive Symptoms:		

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUD Conners' Teacher's Rating Scale Visit	DY Participant ID: Participant Initials: Site: Date:/ NP ID:
1.	Was the Conners' Teacher's form completed and returned?	□₀ No □₁ Yes
2.	How well does the teacher know the child?	$ \Box_1 \text{ Not Well} \\ \Box_2 \text{ Moderately Well} \\ \Box_3 \text{ Very Well} $
3.	How long has the teacher known the child?	Months

Please provide the summary scores from the Conners' Teacher's questionnaire.

		Raw Score	T-Score
4.	Oppositional:		
5.	Cognitive Problems / Inattention:		
6.	Hyperactivity:		
7.	Anxious / Shy:		
8.	Perfectionism:		
9.	Social Problems:		
10.	Conners' ADHD Index:		
11.	Conners' GI Restless – Impulsive:		
12.	Conners' GI Emotional Liability:		
13.	Conners' GI Total		
14.	DSM-IV Inattentive:		
15.	DSM-IV Hyperactive-Impulsive:		
16.	DSM-IV Total:		
17.	Inattentive Symptoms:		
18.	Hyperactive-Impulsive Symptoms:		

C H A T		Part Site Date	icipant l	nitials: / /					
1.	Was the DAS-I	I administer	ed?			□ ₀ No		₁ Yes	
2.	What is the chi	ld's level?				\square_1 Schoo \square_2 Out-of			es 7.0 – 17.11) – 6.11)
3.	What is the chi	ld's handedi	ness?			□ ₁ Right		2 Left	\Box_3 Both
	Core Subtest T-Scores	Ability Score	T-Score	Verbal	Nonverbal Reasoning	Spatial	GCA	SNC	Percentile
4.	Recall of Designs								
5.	Word Definitions								
6.	Pattern Construction \square_1 Std. \square_2 Alt.								
7.	Matrices								
8.	Verbal Similarities								
9.	Sequential & Quantitative Reasoning								
	Cluster / C	omposite S	Scores	Verbal	Nonverbal Reasoning	Spatial	GCA	SNC	

10.	Sum of Core Subtest T-Scores			
11.	Standard Score			
12.	Percentile			

C H A T	Protocol Defined Eligibility Pa BASELINE Sit Da	nrticipant ID: nrticipant Initials: te: nte: / / C ID:	
	sion Criteria: oonses to questions 1 – 4 <u>must</u> be "YES" or "Not Applicable" to meet el	igibility requirements	;)
1.	Is the participant between the ages of 5.0 to 9.99?	\Box_1 Yes	□ ₀ No
2.	 Does the participant have obstructive sleep apnea defined as: a. Obstructive apnea index OAI ≥ 1 or Apnea hyponea index AHI ≥ 2, confirmed on nocturnal, laboratory-based PSG and b. Parental report of habitual snoring (on average occurring > 3 nights per week). 	□ ₁ Yes	□ ₀ No
3.	Does the participant have Tonsillar hypertrophy \geq 2 based on a standardized 0-4 scale:	ł.	
3a.	Does the participant have Tonsillar hypertrophy ≥ 1 based on a standardized 0-4 scale: a. 0 = Surgically absent b. 1 = Taking up < 25% of the airway c. 2 = 25 - 50% of the airway d. 3 = 50-75% of the airway e. 4 = > 75% of the airway	d □₁Yes	□ ₀ No
4.	Has the participant been deemed to be a surgical candidate for AT by ENT evaluation?	□ ₁ Yes	□₀ No
	sion Criteria: oonses to questions 5 – 21 <u>must</u> be "No" or "Not Applicable" to meet el	igibility requirements)

5.	Has the participant had recurrent tonsillitis that meets published ENT clinical practice guidelines for surgery defined as \geq 3 episodes in each of 3 years, 5 episodes in each of 2 years, or 7 episodes in 1 year?	□ ₁ Yes	□ ₀ No
6.	Does the participant have craniofacial anomalies, including cleft lip and palate or sub-mucosal palate le or any anatomic or systemic condition which would interfere with general anesthesia or removal of tonsils and adenoid tissue in the standard fashion?	□ ₁ Yes	□₀ No
7.	Does the participant have obstructive breathing <u>while awake</u> that merits prompt AT in the opinion of the child's physician?	□ ₁ Yes	□ ₀ No
8.	 Does the participant have severe OSAS and significant hypoxemia requiring immediate AT as defined by: a. OAI > 20 or b. AHI > 30, c. Desaturation defined as SaO₂ < 90% for more than 2% sleep time 	□ ₁ Yes	□₀ No
9.	Does the participant have apnea hypopnea indices in the normal range (OAI < 1 and AHI < 2)?	□ ₁ Yes	□ ₀ No

C H A		Protocol Defined Eligibility	Participa	nt ID: nt Initials:	
т			Date: RC ID:	_//_ 	
10.		e participant exhibit evidence of clinically significant cardiac mia on PSG: Non-sustained ventricular tachycardia Atrial fibrillation Second degree AV block Sustained bradycardia < 40 bpm (> 2 minutes) Sustained tachycardia > 140 bpm (> 2 minutes)		□ ₁ Yes	□ ₀ No
11.		articipant extremely overweight defined as: BMI > 2.5 group and sex-z score?			
11a.		articipant extremely overweight defined as: BMI > 2.99 group and sex-z score?		□ ₁ Yes	□ ₀ No
12.	delayed a. Dr b. St fo he c. Th d. Ps of m e. Fo	e participant have severe health problems that could be exacerbat treatment for OSAS including: octor-diagnosed heart disease or cor pulmonale tage II hypertension as defined > 99% percentile (CDC) plus 5 mm r either systolic or diastolic examination, based on the age, gende eight norms, as measured on the baseline exam, or the PSG, or equiring medication herapy for failure to thrive or short stature sychiatric or behavioral disorders requiring or likely to require initia new medication, therapy, or other specific treatment during the 12 onth trial period or school aged children, parental report of excessive daytime sleep	nHg r, and tion 2 piness	□1 Yes	□ ₀ No
13.	in Does the participa a. Se b. Si c. Pe d. Ey e. Di f. Ce ur g. M Su h. Hi of i. Cl	efined as unable to maintain wakefulness, at least three times per routine activities in school or home, despite adequate opportunity e participant have severe chronic health conditions that might ham ation, including: evere cardiopulmonary disorders (e.g.: cystic fibrosis, congenital eart disease) ickle cell anemia oorly controlled asthma (with > 1 hospitalization in last year) pilepsy requiring medication iabetes (type I or type II) requiring medication onditions likely to preclude accurate polysomnography (e.g.: seve ncontrolled pain) ental retardation or enrollment in a formal school Individual Educa lan (IEP) and assigned to a self-contained classroom for all acader ubjects istory of inability to complete cognitive testing and / or score on DA i ≤55 hronic infection or HIV	to sleep. hper tional mic ASII	. □ ₁ Yes	□ ₀ No
14.		e participant have known genetic, craniofacial, neurological or psy ns likely to affect the airway, cognition, or behavior?	chiatric	□ ₁ Yes	□ ₀ No

C H A	CHILDHOOD ADENOTONSILLECTOMY STUD Protocol Defined Eligibility BASELINE	Y Particij Particij Site:	oant ID: oant Initials: 	
Т		Date: _ RC ID:	// 	
15.	Does the participant currently use any of the following medications: a. ADHD medications b. Psychotropic medication (antidepressants, anxiolytics, antips c. Hypnotics d. Hypoglycemic agents or insulin e. Antihypertensives f. Growth Hormone g. Anticonvulsants h. Anti-coagulants i. Daily oral corticosteroids j. Daily medications for pain		□ ₁ Yes	□ ₀ No
16.	Has the participant had previous upper airway surgery on the nose, or larynx, including adenoidectomy. (Ear surgery – e.g.: PE tubes - an exclusion criterion).			
16a.	Has the participant had previous upper airway surgery on the nose or larynx, including tonsillectomy (PE Tubes or prior adenoidectomy not exclusion criteria)?		□ ₁ Yes	□ ₀ No
17.	Has the participant received Continuous Positive Airway Pressure (CPAP) treatment?		□ ₁ Yes	□ ₀ No
18.	Does the participant have a parent or guardian who cannot accompany the child on the night of PSG?		□ ₁ Yes	□ ₀ No
19.	Does the participant have a parent or guardian who cannot read an understand the consent form; including families unable to understand complete the standardized English language assessment forms and instruments?	nd or		
20.	Does the child belong to a family planning to move out of the area withe year?	within	\Box_1 Yes	□ ₀ No
21.	For female participants, has the participant attained menarche by the time of study enrollment per parental report?		□	□ ₀ No cable
Eligi	bility Confirmation:			
22.	Are all of the Inclusion Criteria responses "Yes"?	If No, STOP.	□ ₁ Yes Participant is no	\Box_0 No t eligible.
23.	Are all of the exclusion Criteria responses "No" or "Not Applicable"?		□₁ Yes Participant is no	\Box_0 No t eligible.

C H A T	Fami	TONSILLECTOMY STU ily History SELINE	'UDY Participant ID: Participant Initials: Site: Date: / / /	
_	[Parent / Gu	ardian Completed]	RC ID:	•
1.	Did your child's biological mother smoke cigarette a day while she was pregnant		□₀ No □₁ Yes (1+ per day) □ ₈₈ Not sure)
	 Does your child's current primary at least one cigarette a day? 	caregiver smoke	□₀ No □₁ Yes (1+ per day) □ ₈₈ Not sure)
2.	How many people currently smoke at lea a day in your child's home?	ast one cigarette		
Brot	her and Sister History:			
3.	Does your child have any full brothers a (same mother and father as child)?	nd / or sisters	$\square_0 \text{ No} \square_1 \text{ Yes} \square_{88} \text{ Not sure} $	
	3a. If YES, how many FULL sisters?			
	3b. If YES, how many FULL brothers?	>		
4.	Does your child have any half brothers a (one parent in common with child)?	and / or sisters	□₀ No □₁ Yes □ ₈₈ Not sure	
	4a. If YES, how many HALF sisters?			
	4b. If YES, how many HALF brothers?	?		
5.	Do any of your child's brothers and / or s of the following conditions?	sisters have any	□ ₉₉ Not applicable / Sisters	No Brothers or
			If Yes, plea who has the	
	Conditions	No / Yes	Full Brothers / Sisters	Half Brothers / Sisters
F -		□ ₀ No	1 Sister(s)	[] Sister(s)

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Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

			If Yes, please indicate who has the condition.		
	Conditions	No / Yes	Full Half Brothers / Sisters Brothers / Sisters		
5c.	Anxiety Disorder	□₀ No □₁ Yes □ ₈₈ Not Sure	$___$ \square_1 Sister(s) $__$ $__$ \square_2 Brother(s)	$___\1$ Sister(s) $___\2$ Brother(s)	
5d.	Asthma	□₀ No □₁ Yes □ ₈₈ Not Sure	$___$ \square_1 Sister(s) $__$ $__$ \square_2 Brother(s)	[] ₁ Sister(s) [] ₂ Brother(s)	
5e.	Attention Deficit Hyperactivity Disorder (ADD / ADHD)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	[] ₁ Sister(s) [] ₂ Brother(s)	
5f.	Cancer	□₀ No □₁ Yes □ ₈₈ Not Sure	$__\1$ Sister(s) $__\2$ Brother(s)	[] ₁ Sister(s) [] ₂ Brother(s)	
5g.	Cerebral Palsy	□₀ No □₁ Yes □ ₈₈ Not Sure	$___$ \Box_1 Sister(s) $__$ $\2$ Brother(s)	$____\square_1$ Sister(s) $____\square_2$ Brother(s)	
5h.	Depression	□₀ No □₁ Yes □ ₈₈ Not Sure	$___$ \Box_1 Sister(s) $__$ $\2$ Brother(s)	[] ₁ Sister(s) [] ₂ Brother(s)	
5i.	Diabetes	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	□₁ Sister(s) □₂ Brother(s)	
5j.	Eating Disorder (Anorexia, Bulimia)	□₀ No □₁ Yes □ ₈₈ Not Sure	$___$ \Box_1 Sister(s) $__$ $__$ \Box_2 Brother(s)	$___\1$ Sister(s) $___\2$ Brother(s)	
5k.	Eczema (Atopic Dermatitis)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	$____\square_1$ Sister(s) $____\square_2$ Brother(s)	

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Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

			If Yes, please indicate who has the condition.		
	Conditions	No / Yes	Full Half Brothers / Sisters Brothers / Sisters		
51.	Enlarged Tonsils or Adenoids	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	$__\1$ Sister(s) $__\2$ Brother(s)	
5m.	Excessive Sleepiness (3 or more times per week)	□₀ No □₁ Yes □ ₈₈ Not Sure	$__\1$ Sister(s) $__\2$ Brother(s)	$___\1$ Sister(s) $___\2$ Brother(s)	
5n.	Hay Fever (Nasal Allergies)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	$__\1$ Sister(s) $__\2$ Brother(s)	
50.	High Blood Pressure (Hypertension)	□₀ No □₁ Yes □ ₈₈ Not Sure	[] ₁ Sister(s) [] ₂ Brother(s)	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	
5p.	High Cholesterol	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	[] ₁ Sister(s) [] ₂ Brother(s)	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	
5q.	Insomnia	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	$___$ \square_1 Sister(s) $__$ $__$ \square_2 Brother(s)	$__\1$ Sister(s) $__\2$ Brother(s)	
5r.	Loud Snoring (3 or more times per week)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	$__\1$ Sister(s) $__\2$ Brother(s)	
5s.	Migraine Headache or Chronic Severe Headache	□₀ No □₁ Yes □ ₈₈ Not Sure	[] ₁ Sister(s) [] ₂ Brother(s)	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	
5t.	Narcolepsy	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	[] ₁ Sister(s) [] ₂ Brother(s)	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	
5u.	Sleep Apnea	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	$__\1$ Sister(s) $__\2$ Brother(s)	

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Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

			If Yes, please indicate		
			who has the condition.		
	Conditions	No / Yes	Full	Half	
			Brothers / Sisters	Brothers / Sisters	
5v.	Autism	□₀ No □₁ Yes □ ₈₈ Not Sure	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	[], Sister(s) [] ₂ Brother(s)	
5w.	Aspergers Syndrome	□₀ No □₁ Yes □ ₈₈ Not Sure	$___ \square_1$ Sister(s) $___ \square_2$ Brother(s)	$_$ $_$ \square_1 Sister(s) $_$ $_$ \square_2 Brother(s)	
5x.	Other Significant Medical Conditions:	□₀ No □₁ Yes □ ₈₈ Not Sure	□₁ Sister(s) □₂ Brother(s)	□₁ Sister(s) □₂ Brother(s)	

Parental History:

6. Has either biological parent currently or ever had any of the following conditions?

999 Not Applicable / Information not available

			If Yes, please indicate which parent had the condition.		
	Conditions	No / Yes	Biological Mother	Biological Father	
6a.	Anxiety Disorder	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes	□₀ No □₁ Yes	
6b.	Asthma	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes	□₀ No □₁ Yes	
6c.	Attention Deficit Hyperactivity Disorder (ADD / ADHD)	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes	□₀ No □₁ Yes	
6d.	Cancer	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes	□₀ No □₁ Yes	
6e.	Depression	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes	□ ₀ No □ ₁ Yes	

Participant ID:
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[Parent / Guardian Completed]

			<i>If Yes, please indicate which parent had the condition.</i>			
	Conditions	No / Yes	Biological Mother	Biological Father		
6f.	Diabetes	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes	\square_0 No \square_1 Yes		
6g.	Eczema	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes	□₀ No □₁ Yes		
6h.	Enlarged Tonsils or Adenoids	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes	□₀ No □₁ Yes		
6i.	Excessive Sleepiness (3 or more times per week)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
6j.	Hay Fever (Nasal Allergies)	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes			
6k.	High Blood Pressure (Hypertension)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
61.	High Cholesterol	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
6m.	Heart Disease	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
6n.	Insomnia	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
60.	Loud Snoring (3 or more times per week)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
6р.	Migraine Headache or Chronic Severe Headache	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes		
6q.	Narcolepsy	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes	□₀ No □₁ Yes		

Participant ID:
Participant Initials:
Site:
Date: / /
RC ID: -

[Parent / Guardian Completed]

			If Yes, please indicate which parent had the condition.		
	Conditions	No / Yes	Biological Mother	Biological Father	
6r.	Sleep Apnea	$ \Box_0 No $ $ \Box_1 Yes $ $ \Box_{88} Not Sure $	□₀ No □₁ Yes	□₀ No □₁ Yes	
6s.	Emphysema or Chronic Obstructive Lung Disease	$ \Box_0 No $ $ \Box_1 Yes $ $ \Box_{88} Not Sure $	□₀ No □₁ Yes	□₀ No □₁ Yes	
6t.	Other Significant Medical Conditions:	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes	□₀ No □₁ Yes	

7. What was the mother's height at the time of your child's birth?

____. ___ feet / inches

8. What was the mother's weight at the time of your child's birth?

____. ___. ___ lbs / oz ____₈₈ Not Sure

9. What is the mother's current height?

10. What is the mother's current weight?

____. ___. ___ lbs / oz

____. ___ feet / inches

Child's Respiratory History:

11. In the PAST YEAR, did your child:

		No	Yes	Not Sure
11a.	Usually have a cough?			

Participant ID:
Participant Initials:
Site:
Date: / / /
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[Parent / Guardian Completed]

		No	Yes	Not Sure	
11b.	Usually cough on most days for three (3) consecutive months or more?				
11c.	Usually bring up phlegm from the chest?			 88	
11d.	Bring up phlegm as much as twice a day, four or more times a week, for three (3) consecutive months or more?			88	
11e.	Usually bring up phlegm at all on getting up or first thing in the morning?				
11f.	Have periods or episodes of increased cough and phlegm lasting three (3) weeks or more?	□₀		88	
11g.	Have an attack of wheezing that made him or her feel short of breath?	0		88	If Yes, please answer the following:
11h.	Been troubled by shortness of breath when hurrying on level ground or walking up a slight hill?	0	1	88	$ \begin{array}{c} \square_1 \text{ Rarely} \\ \square_2 \text{ Sometimes} \\ \square_3 \text{ Often} \\ \square_4 \text{ Almost Daily} \end{array} $
11i.	Been troubled by chest tightness?			88	$ \begin{array}{c} $

₀ No
₁ Yes
88 Not Sure

		If Yes, please answer the following:		
		No	Yes	Not Sure
12a.	When your child has a cold?			□ ₈₈
12b.	Occasionally apart from colds?			□ ₈₈
12c.	Most days or nights?	Πo		88

^{12.} In the PAST Year, has your child's chest sounded wheezy or whistling?

Participant ID:
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Site:
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[Parent / Guardian Completed]

		If Yes to Question 12, please answer the following:		
		No	Yes	Not Sure
12d.	With exercise?	Do		88
12e.	Only during the night?			
12f.	With exposure to dust or fumes?			 88
12g.	When exposed to pollen?	Do		88

13. In the PAST YEAR, did any of the following situations cause your child to have a stuffy or runny nose?

		Νο	Yes	Not Sure
13a.	A Smoky Room	Πo		88
13b.	A Dusty Room	Πo		88
13c.	Cold Weather	Πo		88
13d.	Exercise			

Participant ID:
Participant Initials:
Site:
Date: / /
RC ID:

Note – A copy of this form must be submitted to the Vermont Labs with the specimen.

Collection Information:

1. Draw time:

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- 2. Does the participant bleed or bruise easily?
- 3. Has the participant ever been told that they have a disorder related to blood clotting or coagulation?
- 4. Has the participant ever experienced fainting spells while having blood drawn?
- 5. Time at start of venipuncture:
- 6. Elapsed time until tourniquet released:
- 7. Time at end of venipuncture:
- 8. Was any blood drawn?

□₀No]₁ Yes 388 Don't Know □₀ No □₁ Yes 288 Don't Know □₀No ₁ Yes 288 Don't Know 24 Hour Clock 24 Hour Clock 24 Hour Clock \square_1 Yes, full sample \square_2 Yes, partial sample \square_3 No, refused \square_4 No, hard to stick \Box_{98} No, other reason, specify: 10 mL Serum Partial Volume 10 mL EDTA Partial Volume Note if either of these were not done, write ND in space provided.

24 Hour Clock

- Quality of venipuncture:
- 9a. If Quality is Traumatic, please check all that apply:

8a. If Partial Sample was obtained, please specify:

☐1 Traumatic □₂ Clean

☐1 Vein collapse

- \square_2 Hematoma
- $\overline{\square}_{3}^{-}$ Excessive duration of draw \Box_4 Vein hard to get
- \Box_5 Leakage at venipuncture site
- \Box_6 Multiple stick

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CHILDHOOD ADENOTONSILLECTOMY STUDY
Fasting Venipuncture Form
Visit

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

Processing Information:

10. Processing Start Time:

____: EDTA

____: ____SERUM 24 Hour Clock

11. Vial processing information:

	Vial #	Туре	Color	Vol. (mL)	Done	Comments		
11a.	1	SERUM	Clear	1.0mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11b.	2	SERUM	Red	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11c.	3	SERUM	Red	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11d.	4	SERUM	RED	0.5mL	\square_0 No \square_1 Yes	\square_1 Partial Volume \square_2 Hemolysis		
11e.	5	SERUM	RED	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11f.	6	SERUM	RED	0.5mL	\square_0 No \square_1 Yes	\square_1 Partial Volume \square_2 Hemolysis		
11g.	7	SERUM	RED	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11h.	8	SERUM	RED	0.5mL	\square_0 No \square_1 Yes	\square_1 Partial Volume \square_2 Hemolysis		
11i.	9	SERUM	RED	0.5mL	□₀ No □₁ Yes	\square_1 Partial Volume \square_2 Hemolysis		
11j.	10	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11k.	11	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
111	12	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11m.	13	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11n.	14	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
110.	15	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11p.	16	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11q.	17	EDTA	PURPLE	0.5mL	□₀ No □₁ Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11r.	18	EDTA	PURPLE	0.5mL	□₀ No □₁ Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11s.	19	EDTA	PURPLE	0.5mL	\square_0 No \square_1 Yes	\Box_1 Partial Volume \Box_2 Hemolysis		
11t.	20	Packed Cells	WHITE	5.0mL	\square_0 No \square_1 Yes	\square_1 Partial Volume \square_2 Hemolysis		

12. Were samples frozen?

13. Date samples sent to Vermont Lab:

 \Box_0 No \Box_1 Yes

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C H A T		CHILDHOOD ADENOTONSILLECTOMY STUDY Materials Provided Baseline Visit	Participant ID: Participant Initials: Site: Date: / / RC ID:
1.	Were	educational materials provided to the child?	□ ₀ No □ ₁ Yes
2.	Was	Nasal Saline Spray provided to the child?	□₀ No □₁ Yes
	2a.	If Yes, what was the lot number?	
	2b.	Were directions and application uses reviewed with the parent or guardian?	□₀ No □₁ Yes

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Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

1. Has your child ever been diagnosed by a doctor with any of the following?

			If YES to "Ever had this condition", answer these questions:		
	Conditions	Ever had this condition?	Diagnosed or treated by a physician?	Still Present?	Currently taking medication for this condition?
1a.	Acute Life Threatening Episode (ALTE)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure
1b.	Anxiety Disorder	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $
1c.	Asthma	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $
1d.	Attention Deficit Hyperactivity Disorder (ADD / ADHD)	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes □ ₈₈ Not Sure
1e.	Cancer	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes □ ₈₈ Not Sure
1f.	Cerebral Palsy	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \\ \end{array} $	□₀ No □₁ Yes □ ₈₈ Not Sure
1g.	Heartburn or acid reflux	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure
1h.	Depression	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure
1i.	Diabetes	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	$ \Box_0 \text{ No} \Box_1 \text{ Yes} \Box_{88} \text{ Not Sure} $	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure
1j.	Eating Disorder (Anorexia, Bulimia)	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	$ \Box_0 \text{ No} \Box_1 \text{ Yes} \Box_{88} \text{ Not Sure} $	□₀ No □₁ Yes □ ₈₈ Not Sure
1k.	Eczema (Atopic Dermatitis)	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes □ ₈₈ Not Sure
11.	Hay Fever (Nasal Allergies)	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $		□₀No □₁Yes □ ₈₈ Not Sure

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

			If YES to "Ever had this condition", answer these questions:		
	Conditions	Ever had this condition?	Diagnosed or treated by a physician?	Still Present?	Currently taking medication for this condition?
1m.	High Blood Pressure (Hypertension)	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	$ \Box_0 \text{ No} \Box_1 \text{ Yes} \Box_{88} \text{ Not Sure} $	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure
1n.	High Cholesterol	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	$ \Box_0 \text{ No} \Box_1 \text{ Yes} \Box_{88} \text{ Not Sure} $	□₀ No □₁ Yes □ ₈₈ Not Sure
10.	Insomnia	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	$ \Box_0 No $ $ \Box_1 Yes $ $ \Box_{88} Not Sure $	□₀ No □₁ Yes □ ₈₈ Not Sure
1p.	Migraine Headache or Chronic Severe Headache	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure
1q.	Autism	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $	□₀ No □₁ Yes □ ₈₈ Not Sure
1r.	Aspergers Syndrome	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure
	Other Significant Medical Conditions:				
1s.		□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□ ₀ No □ ₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure	□₀ No □₁ Yes □ ₈₈ Not Sure

2. Does your child have allergies?

2a. If Yes, has your child ever been tested (skin or blood) for allergies?

	No
1	Yes

 $\square_0 \text{ No}$ $\square_1 \text{ Yes}$ $\square_{88} \text{ Not Sure}$

2b. If Yes, which of the following tests were positive for allergies (check all that apply):

_ ₁ Molds	\square_2 Trees	\Box_3 Cats	□ ₄ Insects
_₅ Dust	\Box_6 Grass or Pollen	7 Dogs	□ ₈ Food / Drink
] ₉ Latex	\Box_{98} Other, specify:		

Participant	ID:
Participant	Initials:
Site:	
Date:	//
RC ID:	_•

[Parent / Guardian Completed]

3. Has your child ever had Surgery requiring an over night stay?

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	Surgery	Date Performed
За.	Please specify:	//
3b.	Please specify:	//
Зс.	Please specify:	//
3d.	Please specify:	//

4. Has your child ever been referred to any of the following specialists?

		NO	YES
4a.	Cardiologist (Heart Doctor)		
4b.	Gastroenterologist (Stomach Doctor)	□o	
4c.	Pulmonologist (Lung Doctor)	□o	
4d.	Neurologist		
4e.	Otolarynologist (Ear, Nose, & Throat Doctor)		
4f.	Psychiatrist / Psychologist	□o	
4g.	Sleep Specialist		

5.	What was your child's weight at birth?	 _ lbs / oz
6.	Was your child born early (prematurely, or 4 or more weeks early)?	$ \begin{array}{c} \square_0 \text{ No} \\ \square_1 \text{ Yes} \\ \square_{88} \text{ Not Sure} \end{array} $
7.	Did your child need oxygen for more than one day after birth?	□₀ No □₁ Yes □ ₈₈ Not Sure

С	CHILDHOOD ADENOTONSILLECTOMY STUDY	Participant ID:
Н	NEPSY	Participant Initials:
Α	Visit	Site:
Т		Date: / / /
		NP ID:

1. Were any sections of the NEPSY performed?

No
Yes

2. Please indicate the child's hand preference:

]₁ Right
2 Left
3 Ambidextrous
88 Not Established

Please provide the summary scores from the NEPSY for the appropriate subtest

	Subtest	Raw Score	Attn / Exec Scaled Scores	Language Scaled Scores
3.	Phonological Processing			
4.	Tower			
5.	Auditory Attention and Response Set			
6.	Speeded Naming			
7.	Visual Attention			
8.	Comprehension of Instructions			
9.	Sum Scaled Scores			
10.	Core Domain Scores			
11.	Percentile			

* NOTE: For V8, only complete Attn / Exec scores. Please write in ND for the remaining columns for V8. *

12. Please provide the scores for the Arrows sub-section:

____ Raw Score

__ __ Scaled Score

CHILDHOOD ADENOTONSILLECTOMY STUDY NEPSY-II Inhibition Scores Visit ____

Participant ID:				
Participant Initials:				
Site:				
Date: / / /				
NP ID:				

1. Were any sections of the NEPSY-II Inhibition subtest performed?

□₁ Yes

□₀ No

2.	Inhibition Naming	Score
2a.	Inhibition Naming Total Errors Percentile Rank:	
2b.	Inhibition Naming Total Completion Time Scaled Score:	
2c.	Inhibition Naming Combined Scaled Score:	

3.	Inhibition – Inhibition	Score
За.	Inhibition – Inhibition Total Errors Percentile Rank:	
3b.	Inhibition – Inhibition Total Completion Time Scaled Score:	
3c.	Inhibition – Inhibition Combined Scaled Score:	

4.	Inhibition Switching:	Score
4a.	Inhibition – Switching Total Errors Percentile Rank:	
4b.	Inhibition – Switching Completion Time Scaled Score:	
4c.	Inhibition – Switching Combined Scaled Score:	

5.	Inhibition Contrast:	Score
5a.	Inhibition Naming vs. Inhibition – Inhibition Contrast Scaled Score::	
5b.	Inhibition – Inhibition vs. Inhibition – Switching Contrast Scaled Score:	

6. Inhibition Total Error Scaled Score:

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUDY NEPSY-II Word Generation Scores Visit	Participant ID: _ Participant Initia Site: Date:/ NP ID:	lls:		
1.	Were any sections of the NEPSY-II Word Generation subtest performed?	□ ₀ No	□ ₁ Yes		
	Please provide the scores for the following NEPSY-II Word Generation Subtest Items:				
2.	Word Generation Semantic Total Score:				
3.	Word Generation Semantic Scaled Score:				
4.	Word Generation Initial Letter Total Score:				
5.	Word Generation Initial Letter Scaled Score:				
6.	Word Generation Semantic vs. Initial Letter Contrast Scaled Score:				
Participant ID:					

Participant Initials:					
Site:					
Date: / /					
NP ID:					

Please rate each test / questionnaire given for their validity

	Test / Questionnaire Name	Child	Parent	Teacher
1.	Beery VMI (VMI)			
2.	DAS - II (DAS2)	$ \begin{array}{c} $		
<mark>3.</mark>	NEPSY (NEPSY)	☐ ₁ Valid ☐ ₂ Questionable ☐ ₉₉ Not Done		
4.	NEPSY – II Inhibition Scores (NEPSY2)	$ \Box_1 \text{ Valid} \\ \Box_2 \text{ Questionable} \\ \Box_{99} \text{ Not Done} $		
5.	NEPSY – II Word Generation Subtest (NEPWRD)	$ \begin{array}{c} \square_1 \text{ Valid} \\ \square_2 \text{ Questionable} \\ \square_{99} \text{ Not Done} \end{array} $		
6.	WRAML-2 (WRAML2)	$ \Box_1 \text{ Valid} \\ \Box_2 \text{ Questionable} \\ \Box_{99} \text{ Not Done} $		
7.	Purdue Pegboard (PUPEG)	$ \Box_1 \text{ Valid} \\ \Box_2 \text{ Questionable} \\ \Box_{99} \text{ Not Done} $		
8.	CDI (CDI)	$ \begin{array}{c} \square_1 \text{ Valid} \\ \square_2 \text{ Questionable} \\ \square_{99} \text{ Not Done} \end{array} $		
9.	Conners' Parent (CONN)		$ \begin{array}{c} \square_1 \text{ Valid} \\ \square_2 \text{ Questionable} \\ \square_{99} \text{ Not Done} \end{array} $	
10.	Conners' Teacher (CONNTR)			☐ 1 Valid ☐ 2 Questionable ☐ 99 Not Done
11.	BRIEF Parent (BRIEF)		$ \Box_1 \text{ Valid} \\ \Box_2 \text{ Questionable} \\ \Box_{99} \text{ Not Done} $	
12.	BRIEF Teacher (BRITR)			□ 1 Valid □ 2 Questionable □ 99 Not Done

CHILDHOOD ADENOTONSILLECTOMY STUDY Neuropsychological Test Validity Form Visit ____

Participant II	D:
Participant II	nitials:
Site:	
Date:/	/
NP ID:	

	Test / Questionnaire Name	Child	Parent	Teacher
13.	Child Behavior Checklist (CBCL)		$ \begin{array}{c} $	
14.	Pediatric Sleep Questionnaire (PSLQ)		☐ ₁ Valid ☐ ₂ Questionable ☐ ₉₉ Not Done	
15.	Modified Epworth Sleepiness Scale (SLSC)		☐ ₁ Valid ☐ ₂ Questionable ☐ ₉₉ Not Done	
16.	PedsQL – Child Report (ages 5-7) (CHQL1)	☐ ₁ Valid ☐ ₂ Questionable ☐ ₉₉ Not Done / Not Applicable		
17.	PedsQL – Child Report (ages 8-12) (CHQL2)	☐ ₁ Valid ☐ ₂ Questionable ☐ ₉₉ Not Done / Not Applicable		
18.	PedsQL – Parent Report (ages 5-7) (PAQL1)		□1 Valid □2 Questionable □99 Not Done / Not Applicable	
19.	PedsQL – Parent Report (ages 8-12) (PAQL2)		□1 Valid □2 Questionable □99 Not Done / Not Applicable	
20.	OSA-18 Quality of Life (OSAS)			

Comments: _____

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C H A T	CHILDHOOD ADENOTONSILLECTOM Intra Operative Data Sheet Visit	IY STUDY Participant ID: Participant Initials: Site: Date:// RC ID:
1.	Please provide the Surgeon ID:	
2.	What was the pre-operation Adenoid size?	$\Box_1 0 - 32\%$ of nasopharynx occluded $\Box_2 33 - 66\%$ of nasopharynx occluded $\Box_3 67 - 100\%$ of nasopharynx occluded
3.	What was the pre-operation Tonsil size? (Please refer to the photos below)	
[$\Box_1 1 + 0 - 25\%$ $\Box_2 2 + 26 - 50\%$	\Box_3 3+ 51 - 75% \Box_4 4+ 76 - 100%
4.	What surgical technique was used for Adenoid removal?	$\Box_1 \text{ Cautery} \\ \Box_2 \text{ Cold dissection} \\ \Box_3 \text{ Adenoids not removed} \\ \Box_{98} \text{ Other, specify: } \$
	4a. Were adenoids previously removed?	\square_0 No \square_1 Yes
5.	What surgical technique was used for Tonsil removal?	\Box_1 Cautery \Box_2 Cold dissection \Box_{98} Other, specify:
6.	What was the EBL?	□ ₁ <100 cc □ ₉₈ Other(cc)
7.	What was the post-operation Adenoid size?	$\Box_1 0 - 32\%$ of nasopharynx occluded $\Box_2 33 - 66\%$ of nasopharynx occluded $\Box_3 67 - 100\%$ of nasopharynx occluded
8.	Were the tonsils removed completely?	\square_0 No \square_1 Yes

C H A T		CHILDHOOD ADENOTONSILLECTOM Intra Operative Data Sheet Visit	IY STUDY	Participant ID: Participant Initials: Site: Date: / / RC ID:
9.	Were	e digital photos done?	□ ₀ No	□ ₁ Yes
	9a.	If YES, was the digital photo sent to the Surgical QC group?	□ ₀ No	□ ₁ Yes
	9b.	If digital photo was sent, what was the file name?		
10.		e there any complications with the surgical edure?	□₀No	□ ₁ Yes
	10a.	If Yes, please check all that apply:		soft tissue e * e blood loss (>250 cc) blood transfusion OR (control hemorrhage)* ation requiring unanticipated

* Serious Adverse Event, requires immediate action as outlined in the MOP *

OSA-18 Quality of Life Survey

Evaluation of Sleep-Disordered Breathing

Instructions. For each question below, please circle the number that best describes how often each symptom or problem has occurred during the past *4 weeks* (or since the last survey if sooner). Thank you.

	None of the time	Hardly any of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
SLEEP DISTURBANCE							
During the past <i>4 weeks</i> , how often has your child had							
loud snoring?	1	2	3	4	5	6	7
breath holding spells or pauses in breathing at night?	1	2 2	3	4	5	6	7
choking or gasping sounds while asleep?	1 1	2 2	3 3	4 4	5 5	6 6	7 7
restless sleep or frequent awakenings from sleep?	1	2	3	4	5	6	1
PHYSICAL SUFFERING							
During the past 4 weeks, how often has your child had							
mouth breathing because of nasal obstruction?	1	2	3	4	5	6	7
frequent colds or upper respiratory infections?	1	2 2 2 2	3	4	5	6	7
nasal discharge or runny nose? difficulty in swallowing foods?	1 1	2	3	4 4	5 5	6 6	7 7
uincuity in swallowing loous?	I	2	5	4	5	0	1
EMOTIONAL DISTRESS							
During the past 4 weeks, how often has your child had							
mood swings or temper tantrums?	1	2	3	4	5	6	7
aggressive or hyperactive behavior?	1	2 2	3	4	5	6	7
discipline problems?	1	2	3	4	5	6	7
DAYTIME PROBLEMS							
During the past 4 weeks, how often has your child had							
excessive daytime drowsiness or sleepiness?	1	2	3	4	5	6	7
poor attention span or concentration?	1	2	3	4	5	6	7
difficulty getting out of bed in the morning?	1	2	3	4	5	6	7
CAREGIVER CONCERNS							
During the past 4 weeks, how often have the above problems							
	, 1	2	2	4	Б	6	7
caused you to worry about your child's general health? created concern that your child is not getting enough air?	1	2 2	3 3	4 4	5 5	6 6	7 7
interfered with your ability to perform daily activities?	1	2 2 2	3	4	5 5 5	6	7
made you frustrated?	1	2	3	4	5	6	7

OVERALL, HOW WOULD YOU RATE YOUR CHILD'S QUALITY OF LIFE AS A RESULT OF THE ABOVE PROBLEMS? (Circle one number)



CHILDHOOD ADENOTONSILLECTOMY STUDY OSA-18 Quality of Life Survey Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / /
NP ID:

Please answer all of the following questions:

	None of the time	Hardly any of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
Sleep Disturbance							
 During the past 4 weeks, how often has your child had: 							
1a. Loud Snoring?	Do				 4		\Box_6
1b. Breath holding spells or pauses in breathing at night?	□o			\square_3			\square_6
1c. Chocking or gasping sounds while asleep?	D°						\square_6
1d. Restless sleep or frequent awakenings from sleep?	Do			\square_3	4		

Physical Suffering						
2. During the past 4 weeks, how often has						
your child had:						
2a. Mouth breathing because of nasal obstruction?	Πo		3	4	\Box_5	\Box_6
2b. Frequent colds or upper respiratory infections?	□o		\square_3	4		
2c. Nasal discharge or runny nose?	Πo		\square_3		\square_5	\square_6
2d. Difficulty in swallowing foods?	o		3			

Emotional Distress					
 During the past 4 weeks, how often has your child had: 					
3a. Mood swings or temper tantrums?	Do		□3		
3b. Aggressive or hyperactive behavior?	Πo		\square_3		\square_6
3c. Discipline problems?		\square_2			\square_6

Daytime Problems					
 During the past 4 weeks, how often has your child had: 					
4a. Excessive daytime drowsiness or sleepiness?	Do	_ 2	 3		\square_6
4b. Poor attention span or concentration?	Πo		□3		\square_6
4c. Difficulty getting out of bed in the morning?	Πo		□3	\Box_5	\square_6

C H A T

CHILDHOOD ADENOTONSILLECTOMY STUDY OSA-18 Quality of Life Survey Visit ____

Participant ID:
Participant Initials:
Site:
Date:///
NP ID:

	None of the time	Hardly any of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
Caregiver Concerns							
5. During the past 4 weeks, how often have the above problems:							
5a. Caused you to worry about your child's general health?				\square_3		\Box_5	
5b. Created concern that your child is not getting enough air?				\square_3		\square_5	\square_6
5c. Interfered with your ability to perform daily activities?			 2]3			
5d. Made you frustrated?				\square_3		\Box_5	\square_6

6. Overall, how would you rate your child's quality of life as a result of the above problems? (Provide number based on chart below)



CHILDHOOD ADENOTONSILLECTOMY STUDY PedsQL – Parent Report (Ages 5-7) Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / / / _ /
NP ID:

[Parent Completed]

DIRECTIONS:

The following is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for your child during the **past ONE month** by checking the appropriate box below. There are no right or wrong answers. If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a problem has your child had with...

1.	Physical Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
1a.	Walking more than one block?				3	
1b.	Running?				\square_3	
1c.	Participating in sports activity or exercise?				\square_3	
1d.	Lifting something heavy?				\square_3	
1e.	Taking a bath or shower by him or herself?				\square_3	
1f.	Doing chores like picking up his or her toys?					
1g.	Having hurts or aches?					
1h.	Low energy level?				3	4

2.	Emotional Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
2a.	Feeling afraid or scared?					4
2b.	Feeling sad or blue?				3	4
2c.	Feeling angry?	0			3	4
2d.	Trouble sleeping?				3	4
2e.	Worrying about what will happen to him / her?					4

3.	Social Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
3a.	Getting along with other children?					
3b.	Other kids not wanting to be his or her friend?	0			3	4
3c.	Getting teased by other children?	0			3	4
3d.	Not able to do things that other children his or her age can do?	Do			\square_3	4
3e.	Keeping up when playing with other children?				\square_3	

4.	School Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
4a.	Paying attention in class?				\square_3	4
4b.	Forgetting things?					4
4c.	Keeping up with school activities?	0			3	4
4d.	Missing school because of not feeling well?	0		 2	3	4
4e.	Missing school to go to the doctor or hospital?	0		 2	_ 3	4

CHILDHOOD ADENOTONSILLECTOMY STUDY PedsQL – Parent Report (Ages 8-12) Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / /
NP ID:

[Parent Completed]

DIRECTIONS:

The following is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for your child during the **past ONE month** by checking the appropriate box below. There are no right or wrong answers. If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a problem has your child had with...

1.	Physical Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
1a.	Walking more than one block?				3	4
1b.	Running?				\square_3	
1c.	Participating in sports activity or exercise?				\square_3	
1d.	Lifting something heavy?					
1e.	Taking a bath or shower by him or herself?				3	
1f.	Doing chores like picking up his or her toys?					
1g.	Having hurts or aches?					
1h.	Low energy level?				3	4

2.	Emotional Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
2a.	Feeling afraid or scared?				\square_3	4
2b.	Feeling sad or blue?				3	4
2c.	Feeling angry?	0			3	4
2d.	Trouble sleeping?				3	4
2e.	Worrying about what will happen to him / her?					4

3.	Social Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
3a.	Getting along with other children?					
3b.	Other kids not wanting to be his or her friend?	0			3	4
3c.	Getting teased by other children?	0			3	4
3d.	Not able to do things that other children his or her age can do?	Do			\square_3	4
3e.	Keeping up when playing with other children?				\square_3	

4.	School Functioning (problems with):	Never	Almost Never	Sometimes	Often	Almost Always
4a.	Paying attention in class?				\square_3	4
4b.	Forgetting things?				_ 3	4
4c.	Keeping up with school activities?				_ 3	4
4d.	Missing school because of not feeling well?				_ 3	4
4e.	Missing school to go to the doctor or hospital?				_ 3	4

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CHILDHOOD ADENOTONSILLECTOMY STUDY Parent / Household Information BASELINE

Participant ID:				
Participant Initials:				
Site:				
Date: / / /				
RC ID:				

[Parent / Guardian Completed]

Parental Information:

Questions 1 - 4 pertain to the child's birth parents.

1.	What is the mother's ethnicity?	☐ 1 Hispanic or Latino ☐ 2 Not Hispanic or Latino ☐ 88 Not Sure
2.	What is the mother's race?	 American Indian / Native Alaskan Asian Asian Native Hawaiian / Other Pacific Islander Black / African American White / Caucasian Multiracial Not Sure Other, specify:
3.	What is the father's ethnicity?	☐ ₁ Hispanic or Latino ☐ ₂ Not Hispanic or Latino ☐ ₈₈ Not Sure
4.	What is the father's race?	 American Indian / Native Alaskan Asian Native Hawaiian / Other Pacific Islander A Black / African American White / Caucasian Multiracial ₈₈ Not Sure Other, specify:

Household Information:

Questions 5 – 9 pertain to the child's current housing situation.

5. What is your annual household income before taxes?

□ ₁ Under \$5,000
2 \$5,000 to \$9,999
□ ₃ \$10,000 to \$19,999
□ ₄ \$20,000 to \$29,999
□ ₅ \$30,000 to \$39,999
□ ₆ \$40,000 to \$49,999
□ ₇ \$50,000 to \$59,999
\square_8 \$60,000 and above
\square_{97} Prefer not to answer

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CHILDHOOD ADENOTONSILLECTOMY STUDY Parent / Household Information BASELINE

Participant ID:
Participant Initials:
Site:
Date: / /
RC ID:

[Parent / Guardian Completed]

6.	What is the highest level of education completed by the mother?	$ \begin{bmatrix} 1 & 8^{th} & grade & or less than 8^{th} & grade \\ 2 & 9^{th} - 11^{th} & grade \\ 3 & High school diploma or GED \\ 4 & Vocational, trade school, or Associate's degree \\ 5 & Courses toward college degree \\ 6 & Bachelor's Degree or 4-year college degree \\ 7 & Master's Degree \\ 8 & Professional Degree (M.D., Ph.D., J.D., etc) \\ 8 & Not Sure \\ \end{bmatrix} $
7.	What is the highest level of education completed by the father?	$ \begin{bmatrix} 1 & 8^{th} & grade & or less than 8^{th} & grade \\ 2 & 9^{th} - 11^{th} & grade \\ 3 & High school diploma or GED \\ 4 & Vocational, trade school, or Associate's degree \\ 5 & Courses toward college degree \\ 6 & Bachelor's Degree or 4-year college degree \\ 7 & Master's Degree \\ 8 & Professional Degree (M.D., Ph.D., J.D., etc) \\ 8 & Not Sure \\ \end{bmatrix} $
8.	What is the mother's current employment status?	 Working full-time (35 or more hours per week) Working part-time (35 or less hours per week) Home keeper Unemployed, looking for work Unemployed, not looking for work Student Retired Numble to work, specify: Not Sure
9.	What is the father's current employment status?	 1 Working full-time (35 or more hours per week) 2 Working part-time (35 or less hours per week) 3 Home keeper 4 Unemployed, looking for work 5 Unemployed, not looking for work 6 Student 7 Retired 8 Unable to work, specify:

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CHILDHOOD ADENOTONSILLECTOMY STUDY Physical Examination Baseline Visit

Participant ID:				
Participant Initials:				
Site:				
Date: / / /				
RC ID:				

- 1. Temp: _____° C
- 2. Pulse: _____
- 3. Resp: _____

SYSTEM	NORMAL	ABNORMAL (explain)	NOT DONE
4. Constitutional		□ ₂	99
5. Skin		□ ₂	99
6. HEENT		□ ₂	99
7. Neck		□ ₂	99
8. Respiratory (Not OSAS)		□ ₂	99
9. Cardiovascular		□ ₂	99
10. Abdomen		<u></u>	9 9
11. Musculoskeletal		<u></u>	9 99
12. Extremities		□ ₂	99
13. Lymphatics			99
14. Neurologic			99

15. What is the Friedman palate position? (Please refer to the photos below)



 \Box_1 Position I



2 Position II

99 Not Done



 \square_3 Position III



4 Position IV

CHILDHOOD ADENOTONSILLECTOMY STUDY Physical Examination Baseline Visit

Participant ID:				
Participant Initials:				
Site:				
Date: / / /				
RC ID:				

16.	 What is the Mallampati position? (Please refer to the photos below) 		□ ₉₉ Not Done		
	□ ₁ Class I	□ ₂ Class II		ass III	□₄ Class IV
17.	Does the child have any kn	own allergies?		□ ₀ No	□ ₁ Yes
	17a. If Yes, what allergies	(check all that apply):			
	□ ₁ Molds □ ₅ Dust □ 9 Latex	\square_2 Trees \square_6 Grass or \square_{98} Other, s		\square_3 Cats \square_7 Dogs	\square_4 Insects \square_8 Food / Drink

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Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

- 1. Temp: ____ ° C
- 2. Pulse: ____ ___
- 3. Resp: _____

SYSTEM	NORMAL	ABNORMAL (explain)	NOT DONE
4. Constitutional		□2	99
5. Skin		□ ₂	99
6. HEENT		□ ₂	99
7. Neck		□ ₂	99
8. Respiratory (Not OSAS)		□2	99
9. Cardiovascular			99
10. Abdomen		□ ₂	99
11. Musculoskeletal		□ ₂	99
12. Extremities		□ ₂	99
13. Lymphatics		□ ₂	99
14. Neurologic		□ ₂	99

15. Since	5. Since the last visit, has the child developed any allergies?				□ ₁ Yes
15a.	15a. If Yes, what allergies (check all that apply):				
	☐ 1 Molds ☐ 5 Dust ☐ 9 Latex	□₄ Insects □ ₈ Food / D	Drink		
 16. Since the last visit, has the child begun any new or alternative medical treatments? □₀ No □₁ Ye 					
16a. If Yes, what treatment:					
\square_1 Nasal Steroids \square_2 CPAP or BIPAP \square_4 Oral Device \square_5 Surgery (other than TA) \square_{98} Other, specify:			□ ₃ Oxygen	Therapy _	

 1. Since your last visit (/ /), how often has your child snored during sleep?), how often					
2a. If Yes, approximately how many times per week? \Box_1 More than 7 times	er week) r week)				
$\Box_{3} 4 - 2 \text{ times}$ $\Box_{4} 1 \text{ time}$ $\Box_{88} \text{ Not sure}$					
2b. What time of day does the child use the spray? 1 Mostly at night 2 Mostly in the morning 3 Throughout the day 88 Not sure					
 3. Has your child had any new medical problems, hospitalizations, or Emergency Room visits since your last visit (//)? 3a. If Yes, list:					
Note – if a condition is recorded above, add it to the AE form					
4. Has the child begun any new medications? $\Box_0 No$ $\Box_1 Yes$					
4a. If Yes, list:					
 Since your last visit (/ / /), has your child had any of the following during sleep? 					
NeverRarely (less than once a week)Sometimes (1 to 2 times per week)Frequently (3 to 4 times per week)Alway Almost A (5 to 7 times week)	ways Not es per Sure				
5a.Chest is wheezy or whistling \square_0 \square_1 \square_2 \square_3					
5b.Frequent Awakenings \Box_0 \Box_1 \Box_2 \Box_3 \Box_4					
5c.Stop Breathing \Box_0 \Box_1 \Box_2 \Box_3 \Box_2					
5d. Daytime Sleepiness \Box_0 \Box_1 \Box_2 \Box_3					

Comments:

C H A T	CHILDHOOD ADENOTONSILLECTOMY S Post-Op Phone Call Visit	F S C	Participant ID:
1.	Please provide the Surgeon ID:		·
2.	After their adenotonsillectomy, did the child require evaluation in the ER, other surgery or admission to the hospital for any reason or did they require evaluation in the ENT clinic for any reason other than a routine post- operative follow-up visit?	□₀No	□ ₁ Yes
	2a. If Yes, what was the reason?		hydration requiring IV Fluid hydration requiring Admission* eeding requiring Admission* eeding requiring return to OR* her Admission*, specify:
		□ ₉₈ Ot	ther, specify:
	* Serious Adverse Event, requ	ires immedia	ate action as outline in the MOP *
3.	Did the child have post operative pain requiring pain medication for greater than 3 weeks after surgery?	□ ₀ No	□ ₁ Yes
4.	Are there any current eating or drinking concerns?	□₀ No	□ ₁ Yes
	4a. Has this concern required evaluation or care by a medical professional?	□₀ No	□ ₁ Yes
5.	Are there any current concerns about the child's voice?	□₀No	□ ₁ Yes
	5a. Has this concern required evaluation or care by a medical professional?	□₀No	□ ₁ Yes
6.	Has the breathing or snoring of the child worsened since surgery?	□₀ No	□ ₁ Yes
7.	· · · · · · · · · · · · · · · · · · ·	\square_0 No nts, please co	\Box_1 Yes omplete an Adverse Event form.
8.	Has the child begun any new medications? If Yes, plea	□ ₀ No ase complete	\Box_1 Yes ethe CMED form.
Co	mments:		

C H A T		CHILDHOOD ADENOTONSILL Post-Op Phone (Visit		Participa Site: Date:	ant ID: ant Initials: //
1.	Plea	se provide the Surgeon ID:			
2.	eval hosp the E	their adenotonsillectomy, did the child require uation in the ER, other surgery or admission to tital for any reason or did they require evaluatio ENT clinic for any reason other than a routine po ative follow-up visit?	n in ost-	No	□ ₁ Yes
	2a.	If Yes, what was the reason?		Other Adm	ission*, specify:
			9	₀Other, spe	cify:
		* Serious Adverse I	Event, requires imm	ediate actio	on as outline in the MOP *
3.	Aret	there any current eating or drinking concerns?		No	□ ₁ Yes
	За.	Has this concern required evaluation or care by a medical professional?		No	□ ₁ Yes
4.	Aret	there any current concerns about the child's voi	ce? □₀	No	□ ₁ Yes
	4a.	Has this concern required evaluation or care by a medical professional?		No	□ ₁ Yes
5.		the breathing or snoring of the child worsened e surgery?		No	□ ₁ Yes
6.		e past 30 days, have there been any other majo erns? If Yes and neco			\Box_1 Yes an Adverse Event form.
7.		e past 30 days, has the child begun any new ications?	□₀ If Yes, please comp		□ ₁ Yes IED form.

Comments: _____

C H A T	H Pre-Operative Questionnaire SCREEN			Participant ID: Participant Initials: Site: Date:// RC ID:
1.	How was this information obtained?		\square_1 Chart Rev \square_2 Current El	iew from previous ENT evaluation NT evaluation
2.	What was the pre-operation Tonsil (Please refer to the photos below)	size?	□ ₉₉ Not Done	•
	$\Box_1 1+0-25\%$	26 – 50%	□ ₃ 3+51 – 75%	$\Box_4 4 + 76 - 100\%$
3.	Is the child a candidate for Adenotons	illectomy?	□ ₀ No	□ ₁ Yes
4.	Are there any known contraindication	s for surgery?	□ ₀ No	□₁Yes
5.	What is the Surgeon ID?			

C H A T	H Pediatric Sleep Questionnaire A Visit		Participant In):
1.	 While sleeping, does your child: 1a. Snore more than half the time? 1b. Always snore? 1c. Snore loudly? 1d. Have "heavy" or loud breathing? 1e. Have trouble breathing, or struggle to breathe? 	$ \begin{array}{c} 1_1 Yes \\ 1_1 Yes $	□ 0 No □ 0 No □ 0 No □ 0 No □ 0 No	 Base Don't Know
2.	Have you ever seen your child stop breathing during the night?	□ ₁ Yes	□₀ No	□ ₈₈ Don't Know
3.	Does your child:3a. Tend to breathe through the mouth during the day?3b. Have a dry mouth on waking up in the morning?3c. Occasionally wet the bed?	□₁ Yes □₁ Yes □₁ Yes	□₀ No □₀ No □₀ No	□ ₈₈ Don't Know □ ₈₈ Don't Know □ ₈₈ Don't Know
4.	Does your child:4a. Wake up feeling unrefreshed in the morning?4b. Have a problem with sleepiness during the day?	□ ₁ Yes □ ₁ Yes	□₀ No □₀ No	□ ₈₈ Don't Know □ ₈₈ Don't Know
5.	Has a teacher or other supervisor commented that your child appears sleepy during the day?	□ ₁ Yes	□₀ No	□ ₈₈ Don't Know
6.	Is it hard to wake your child up in the morning?	□ ₁ Yes	□ ₀ No	□ ₈₈ Don't Know
7.	Does your child wake up with headaches in the morning?	□ ₁ Yes	□ ₀ No	□ ₈₈ Don't Know
8.	Did your child stop growing at a normal rate at any time since birth?	□ ₁ Yes	□ ₀ No	□ ₈₈ Don't Know
9.	Is your child overweight?	□ ₁ Yes	□ ₀ No	□ ₈₈ Don't Know
10.	 This child OFTEN: 10a. Does not seem to listen when spoken to directly. 10b. Has difficulty organizing tasks and activities. 10c. Is easily distracted by extraneous stimuli. 10d. Fidgets with hands or feet or squirms in seat. 10e. Is "on the go" or often acts as if "driven by a motor". 10f. Interrupts or intrudes on others (eg: butts into conversations or games). 	□1 Yes □1 Yes □1 Yes □1 Yes □1 Yes □1 Yes	□ 0 N0 □ 0 N0 □ 0 N0 □ 0 N0 □ 0 N0 □ 0 N0	 B88 Don't Know

Site:	
Date: _	//
RC-ID:	•

Prescreening & Screening Summary

These data should be collected and entered into the Prescreening & Screening Summary Module in the DMS biweekly, by the End of Business on Friday. These data will help provide monthly reports on enrollment, recruitment, and retention per site for the duration of the study.

Pre-Screening Data:

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1.	How many participant contacts were made by site staff this week (please indicate the number for each of the contact methods listed below):					
	1a.	Participants recruited through chart review:				
	1b.	Participants recruited through clinic referral (ENT, PSG,				
	1c.	Participants recruited through CHAT flyers, brochures, or other media:				
	1d.	Participant recruited through other means:				
		Describe other means:				
	1e.	Total number of participants contacted:	ns 1a – 1d.			
2.		t is the status of the participants contacted above (please indicate the number fo gory below):	r each			
	2a.	Participants eligible for screening:				
	2b.	Participants not eligible for screening:				

 2c.
 Participants not interested in participating:

2d. Total number of participants assessed for screening:

Note: Add columns 2a – 2c.

Screening Data:

- 3. How many of the screened participants were eligible for randomization:
- 4. How many of the screened participants were *not* eligible for randomization:

С	CHILDHOOD ADENOTONSILLECTOMY STUDY	Participant ID:
н	Purdue Pegs	Participant Initials:
Α	Visit	Site:
Т		Date: / / /
		NP ID:

1. Was this test performed?

2.

□₀ No □₁ Yes

For Question 2, please provide the summary scores from the Purdue Pegboard test

HandNumber of Pegs2a.Dominant Hand: $\Box_1 \operatorname{Right}_2 \operatorname{Left}$ _____2b.Non-dominant Hand: $\Box_1 \operatorname{Right}_2 \operatorname{Left}$ _____2c.Both Hands:__________

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUE Randomization	DY Participant ID: Participant Initials: Site: Date: / / RC ID:
1.	Has the participant met all eligibility criteria and signed the consent form; and the PI has reviewed and certified the individual as being eligible?	□ ₀ No □ ₁ Yes
2.	Has the participant had an ENT evaluation within 90 days of baseline, and is considered a candidate for surgery?	□₀ No □₁ Yes
3.	Has the participant had an overnight PSG evaluation, and is within the protocol defined limits?	□₀ No □₁ Yes
4.	Was the child able to perform the neurocognitive testing?	□₀ No □₁ Yes
5.	Date the parent signed the consent form:	$\overline{M} \overline{M} / \overline{D} \overline{D} / \overline{Y} \overline{Y} \overline{Y} \overline{Y} \overline{Y}$
6.	Date of Randomization:	$\overline{M} \overline{M} / \overline{D} \overline{D} / \overline{Y} \overline{Y} \overline{Y} \overline{Y} \overline{Y}$
7	Dendemization Code assigned by DMS:	

7. Randomization Code assigned by DMS:

C H A T	CHILDHOOD ADENOTONSILLE Reevaluation for Surgical (Visit T2	Candidacy I	Participant ID: Participant Initials: Site: Date: / / RC ID:	
1.	Was reevaluation for surgical candidacy performed?	□ ₀ No		
2.	What was the current Tonsil size? (Please refer to the photos below)	□ ₉₉ Not Done		
	$\Box_1 1+0-25\%$	□ ₃ 3+51 – 75%	4 4+ 76 − 100%	
3.	Is the child still considered to be a candidate for Adenotonsillectomy?	□ ₀ No	□ ₁ Yes	
4.	Are there any known contraindications for surgery?	□ ₀ No	□ ₁ Yes	
5.	What is the Surgeon ID?			

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUDY Referral Source and Demographics SCREEN		Participant ID: Participant ID: Participant Initials: Site: Date: / / RC ID:
1.	Participant was recruited from which source:	$\square_{1} \text{OTL}$ $\square_{2} \text{Sleep Clinic}$ $\square_{3} \text{Sleep Lab}$ $\square_{4} \text{Pediatric Clini}$ $\square_{5} \text{Community}$ $\square_{6} \text{Advertisemen}$ $\square_{7} \text{Chart Review}$ $\square_{98} \text{Other, specified}$	it
2.	What is the child's Date of Birth?	<u></u> / <u></u> / <u></u> / <u></u> / <u></u>	Y Y Y Y
3.	What is the Screening PSG date?	<u> </u>	Y Y Y
4.	What is the child's race?	\square_2 Asian \square_3 Native Hawaii \square_4 Black / African \square_5 White / Cauca \square_6 Multiracial	
5.	What is the child's ethnicity?	\square_1 Hispanic or L \square_2 Not Hispanic	
6.	What is the child's standing height? *	cn	n
7.	What is the child's weight? *	kg	1
8.	What is the child's BMI? *	·	
	* Indicate measurement at time of PSG screening.		
9.	What is the child's gender?	\square_1 Male \square_2 Female	

Participant ID:
Participant Initials:
Site:
Date: / /
RC ID:

[Parent / Guardian Completed]

Please maintain this log for 5 consecutive days. Complete these questions first thing in the morning of each day.

1.	Pleas	e provi	de the day:			Enter a number fr	om 1 - 5	
2.	What	is toda	y's date?				<u>, , , , , , , , , , , , , , , , , , , </u>	
3.	At wh last ni		did your child go to bed a	and try to fall asleep)	::	1 AM	$\square_2 PM$
4.	Did yo	our chile	d wake up during the nigh	nt?		□₀No	\Box_1 Yes	
	4a.	If YES	, please provide the times	8:	1)	::	D 1 AM	$\square_2 PM$
					2)	::	1 AM	$\square_2 PM$
					3)	::	1 AM	$\square_2 PM$
5.	What	time di	d your child first wake up	today?		::	1 AM	$\square_2 PM$
6.	Did yo	our chile	d go back to sleep after fi	rst waking up?		□ ₀ No	□ ₁ Yes	
	6a.	If YES	, what time did they get u	p and out of bed?		::	1 AM	$\square_2 PM$
7.	Did yo	our chile	d take any naps yesterdag	y?		□ ₀ No	□ ₁ Yes	
	If YES	S, pleas	e provide the times:					
			Nap Beg	jin		Nap	End	
		7a.	: □ ₁ AM	□ ₂ PM		: □₁ A	AM 🛛 2 P	М
		7b.	: 🔲 AM	□ ₂ PM		: □ ₁ A	AM 🛛 2 P	М
8.	Did yo	our chile	d go to school yesterday?	,		□ ₀ No □ ₉₉ Not Ap	□ ₁ Yes plicable / Child n	ot in school
9.	Was y	your ch	ild sick yesterday?			□₀No	□ ₁ Yes	
	9a.	If YES	, with what?					
10.	Did yo	our chile	d take any medication(s)	yesterday?		□ ₀ No	□ ₁ Yes	
	10a.	If YES	, list medication(s):					
11.	How many 8oz (1 cup) caffeinated beverages did your child drink yesterday?							

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CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire BASELINE

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

1. During the past 6 months, at what time, on average has your child:

		Weekdays:	Weekends:
1a.	Gone to bed?	:	:
	(first closed the eyes in attempt to fall asleep)	□_1 AM □_2 PM	□_1 AM □_2 PM
1b.	Fallen asleep?	: □_1 AM □_2 PM	: □_1 AM □_2 PM
1c.	Woken up?	:	:
	(after the sleep period)	□_1 AM □_2 PM	□_1 AM □_2 PM

2. Has your child snored in the last month?

₀ No
1 Yes
88 Not sure

If Yes, answer 2a – 2d; referring to your child's snoring in the last month:

2a.	How often has your child experienced loud snoring during sleep?	$\Box_{0} \text{ Never}$ $\Box_{1} \text{ Rarely (less than once a week)}$ $\Box_{2} \text{ Sometimes (1 to 2 times per week)}$ $\Box_{3} \text{ Frequently (3 to 4 times per week)}$ $\Box_{4} \text{ Always or Almost Always (5 to 7 times per week)}$ $\Box_{88} \text{ Not Sure}$
2b.	Has your child's snoring usually been:	\Box_1 Only slightly louder than heavy breathing \Box_2 About as loud as mumbling or talking \Box_3 Louder than talking \Box_4 Extremely loud – can be heard through closed doors \Box_{88} Not Sure
2c.	Has the snoring sounded:	\Box_1 The same with each breath (snore) \Box_2 Sometimes loud, sometimes soft \Box_{88} Not Sure
2d.	Was your child's snoring so loud it disturbed others?	□₀ No □₁ Yes □ ₈₈ Not sure
	old was your child when he / she first ed snoring?	years 🛛 88 Not sure

3.

C H A T		CHILDHOOD ADENOTONSILL Sleep and Health Ques BASELINE [Parent / Guardian Col	tionnaire	Participant ID: Participant Initials: Site: Date: / / RC ID:
	За.	During the entire time your child has snored, has his / her snoring usually been?	\square_2 About as loud as \square_3 Louder than talking	er than heavy breathing mumbling or talking ng can be heard through closed doors
	3b.	Has your child's snoring EVER been so loud it disturbed others?	□₀ No □₁ Yes □ ₈₈ Not sure	
	If Ye: 3c.	s, answer 3c: Approximately how many years has the snoring been this loud?	years 🛛 88	Not sure
4.	4. Do you watch your child while he / she is asleep at night because you are afraid about his / her breathing?			was younger than 5 years old

5. In the **PAST YEAR**, has your child had the following:

		No	Yes	Not Sure
5a.	Frequent colds or flu?	□o		□ ₈₈
5b.	Frequent ear infections?	Do		
5c.	Difficulty swallowing?	Do		
5d.	Speech problems?			

		No	Yes	Not In School	Not Sure
5e.	Difficulties with school work related to attention problems or sleepiness?	□o			88
5f.	Difficulties with school work related to behavior problems?		 1	_ 2	
5g.	Difficulties interacting with others or in a group setting because of behavior problems?	□o			88

CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire BASELINE

Participant ID: ______ Participant Initials: _____ Site: ____ Date: ____ / ____ / ____ RC ID: ____ - ___

[Parent / Guardian Completed]

		No	Yes	Not Sure
5h.	Extreme irritability or mood problems?			□ ₈₈
5i.	Has your child been professionally counseled for a behavior problem?	□₀		
5j.	Has your child been referred for special help in school?	Do		88

6. Over the **PAST MONTH**, has your child had any of the following during sleep?

		Never	Rarely (less than once a week)	Sometime s (1 to 2 times per week)	Frequently (3 to 4 times per week)	Always or Almost Always (5 to 7 times per week)	Not Sure
6a.	Breathing difficulty	□o			\square_3	4	
6b.	Chest is wheezy or whistling	Do		_ 2	\square_3	 4	88
6c.	Frequent Awakenings	□o			\square_3	4	88
6d.	Frequent tossing, turning, or thrashing?	Do	 1	_ 2	□3	4	88
6e.	Heartburn	□o			\square_3	4	88
6f.	Legs are jumpy or jerky				□3	4	88
6g.	Restlessness				\square_3	4	
6h.	Talk during sleep				\square_3	4	
6i.	Walk during sleep				□3	_ 4	88

7. At what time of day does your child function best?

1 Morning
2 Afternoon

__₃ Evening

 \square_4 No best time

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CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire BASELINE

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

8. In the **PAST 3 Months**, on average, how much time has your child spent doing the following: Note: Enter 0 if you did not do any of the activities below

		Amount of Time Per Day	Number of Days Per Week
8a.	Walking for exercise or to school	HM	D
8b.	Jogging or running	HM	D
8c.	Bicycling	HM	D
8d.	Basketball, volley ball or other sports involving running or jumping	HM	D
8e.	Swimming	HM	D
8f.	Jump rope	HM	D
8g.	In gym class or PE, being active	HM	D
8h.	Other activity (specify):	HM	D

- 9. On average how many beverages containing caffeine (cola, coffee, tea, etc.) does your child drink per day?
 ** One can of soda = 1.5 cups; 1 20oz bottle = 2.5 cups **
- 0 None

 \Box_1 Less than one cup per day

 \square_2 Approximately one cup (8oz) per day

□₃ More than one cup, but not more than three cups per day

 \square_4 More than three cups per day

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

1. Since your last visit, at what time, on average has your child:

_		Weekdays:	Weekends:
1a.	Gone to bed?	:	:
	(first closed the eyes in attempt to fall asleep)	□_1 AM □_2 PM	□_1 AM □_2 PM
1b.	Fallen asleep?	: □_1 AM □_2 PM	: □_1 AM □_2 PM
1c.	Woken up?	:	:
	(after the sleep period)	□_1 AM □_2 PM	□_1 AM □_2 PM

2. Has your child snored in the last month?

₀ No
1 Yes
88 Not sure

□₀Never

₈₈ Not Sure

If Yes, answer 2a – 2d; referring to your child's snoring in the last month:

2a. In the last month, how often has your child experienced loud snoring during sleep?

2b.	In the last month, has your child's snoring	
	usually been:	

2c. In the last month, has the snoring sounded:

$ \begin{array}{c} \label{eq:2.1} \Box_1 \mbox{Only slightly louder than heavy bre} \\ \mbox{\Box_2} \mbox{About as loud as mumbling or talki} \\ \mbox{\Box_3} \mbox{Louder than talking} \\ \mbox{\Box_4} \mbox{Extremely loud - can be heard thre} \\ \mbox{\Box_{88}} \mbox{Not Sure} \\ \end{array} $	ng
The same with each breath (snore) \square_2 Sometimes loud, sometimes soft \square_{88} Not Sure)

 \square_4 Always or Almost Always (5 to 7 times per week)

 $\Box_1 \text{ Rarely (less than once a week)} \\ \Box_2 \text{ Sometimes (1 to 2 times per week)} \\ \Box_3 \text{ Frequently (3 to 4 times per week)}$

2d. In the last month, was your child's snoring so loud it disturbed others?

3. Do you watch your child while he / she is asleep at night because you are afraid about his / her breathing?

 \square_0 No \square_1 Yes \square_2 Only when child was younger than 5 years old

CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

4. In the **PAST 6 MONTHS**, has your child had the following:

		No	Yes	Not Sure
4a.	Frequent colds or flu?	Do		
4b.	Frequent ear infections?	Do		
4c.	Difficulty swallowing?	Do		
4d.	Speech problems?	Do		

		No	Yes	Not In School	Not Sure
4e.	Difficulties with school work related to attention problems or sleepiness?	Do	1	 2	88
4f.	Difficulties with school work related to behavior problems?				□ ₈₈
4g.	Difficulties interacting with others or in a group setting because of behavior problems?	Do	 1	_ 2	88

		No	Yes	Not Sure
4h.	Extreme irritability or mood problems?			□ ₈₈
4i.	Has your child been professionally counseled for a behavior problem?	0		
4j.	Has your child been referred for special help in school?	Do		□88

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CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / /
RC ID:

[Parent / Guardian Completed]

5. Over the PAST MONTH, has your child had any of the following during sleep?

		Never	Rarely (less than once a week)	Sometimes (1 to 2 times per week)	Frequently (3 to 4 times per week)	Always or Almost Always (5 to 7 times per week)	Not Sure
5a.	Breathing difficulty	Πo				4	88
5b.	Chest is wheezy or whistling	Πo			\square_3	4	
5c.	Frequent Awakenings				□3	_ 4	
5d.	Frequent tossing, turning, or thrashing?	Do	□ 1	_ 2	_ 3	4	88
5e.	Heartburn	Πo		 2	\square_3	4	88
5f.	Legs are jumpy or jerky	Πo		_ 2		4	88
5g.	Restlessness	Πo			\square_3	4	88
5h.	Talk during sleep	Πo			\square_3	4	
5i.	Walk during sleep	Πo			 3	4	88

6. At what time of day does your child function best?

□ ₁ Morning
2 Afternoon
□ ₃ Evening
4 No best time

CHILDHOOD ADENOTONSILLECTOMY STUDY Sleep and Health Questionnaire Visit ____

Participant ID:
Participant Initials:
Site:
Date: / / / _ /
RC ID:

[Parent / Guardian Completed]

7. In the **PAST 3 Months**, on average, how much time has your child spent doing the following: Note: Enter 0 if you did not do any of the activities below

		Amount of Time Per Day	Number of Days Per Week
7a.	Walking for exercise or to school	HM	D
7b.	Jogging or running	HM	D
7c.	Bicycling	HM	D
7d.	Basketball, volley ball or other sports involving running or jumping	HM	D
7e.	Swimming	HM	D
7f.	Jump rope	HM	D
7g.	In gym class or PE, being active	НМ	D
7h.	Other activity (specify):	HM	D

- 8. On average how many beverages containing caffeine (cola, coffee, tea, etc.) does your child drink per day?
 ** One can of soda = 1.5 cups; 1 20oz bottle = 2.5 cups **
- 0 None

 \Box_1 Less than one cup per day

 \square_2 Approximately one cup (8oz) per day

□₃ More than one cup, but not more than three cups per day

 \square_4 More than three cups per day

CHILDHOOD ADENOTONSILLECTOMY STUDY	Participant ID:
Modified Epworth Sleepiness Scale	Participant Initials:
Visit	Site:
	Date: / / /
[Parent Completed]	RCID: -

How likely is your child to actually doze off or fall asleep in the following situations, *in contrast to feeling just tired*? This refers to his / her usual way of life in recent times. Even if he / she has not done some of these things recently, think about how they would have affected your child. Use the following scale to choose the *most appropriate number* for each situation:

It is important that you check ONE box (0 to 3) for each of the 10 questions:

		Chance of Dozing or Falling Asleep				
		NoSlightModerateHigChanceChanceChanceChance				
1.	Sitting and reading	□o			□3	
2.	Watching TV	Πo			3	
3.	Sitting, inactive in a public place (ergo: a class room or a movie theater)				\square_3	
4.	As a passenger in a car for an hour without a break	Πo			\square_3	
5.	Lying down to rest in the afternoon when circumstances permit	Πo	1		\square_3	
6.	Sitting and talking to someone	Πo			\square_3	
7.	Sitting quietly after lunch	Πo			□3	
8.	In a car, while stopped for a few minutes in traffic	Πo			□3	
9.	Doing homework or taking a test	Πo			\square_3	
10.	Playing a videogame	Πo			\square_3	

C H A T

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUD Sleep Journal Summary Visit	Participant ID: Participant Initials: Site: Date: / RC ID:
1.	Were the parent completed sleep journals returned?	□₀ No □₁ Yes
2.	Were the journals recorded for 5 days?	□₀ No □₁ Yes

2a. If No, how many days were recorded?

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUI Study Stop	DY Participant ID: Participant Initials: Site: Date:// RC ID:
1.	Did the participant complete the study, as per protocol? 1a. If No, what was the last study visit the participant completed?	□ ₀ No □ ₁ Yes
2.	Date the participant stopped:	$-\overline{M} - \overline{M} - \overline{D} - \overline{D} - \overline{V} - \overline{Y} - \overline{Y} - \overline{Y} - \overline{Y}$
3.	What was the primary reason that the participant stopped?	 Participant successfully completed all required study visits Participant lost to follow-up Participant withdrew consent Protocol defined stopping rules, decrease in DASII performance Screen failure as defined in MOP New medical problem determined to make continued participation unsafe New behavioral or learning problem determined to make continued participation unsafe Participant declined their assigned randomization arm Death Other, specify:

Comments:

NOTE: This form should <u>only</u> be completed after a participant has been **RANDOMIZED**.

1. Date the participant's treatment stopped:

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- 2. What is the primary reason that the participant's treatment was stopped?
 - □ Child's physician has identified a change in signs or symptoms that warrants alternative treatment for OSA (Initiation of CPAP for example)
 - 2 Child has developed new academic or behavioral problems resulting in a recommendation for grade retention
 - \square_3 Child has begun special education
 - \square_4 Child has begun counseling or placement on medications for behavior or emotional problems
 - ☐₅ Recurrent bacterial tonsillitis (3 or more episodes of streptococcal culture positive infection occurring over a 3 month period)
 - 6 New clinical diagnosis of cor pulmonale
 - \Box_7 Development of "failure to thrive" defined by weight loss during the course of follow-up
 - \square_8 New onset Stage 2 Hypertension, which is not better explained by another medical condition \square_9 New onset hypersomnolence defined as reports of falling asleep on average > 3 times per week, which is not better explained by other factors unrelated to OSA

)				,				-	
10	Parent /	Caregiver	decision to	have	Adeno	tonsillect	omy Sı	urgery	(WWSC	group)

- \Box_{11} Parent / Caregiver decision to not have Adenotonsillectomy Surgery (EAT group)
- 98 Other medical or neuropsychological necessitated reason, specify:

3.	Has the Medical Monitor confirmed this to be a treatment failure?	□ ₀ No	□ ₁ Yes
4.	Did this participant crossover?	□ ₀ No	□ ₁ Yes
	4a. If yes, please indicate the primary reason:	failure	due to confirmed treatment due to parent / caregiver
5.	Will the participant be continuing with follow-up visits?	□₀ No	□ ₁ Yes

Comments: _____

CHILDHOOD ADENOTONSILLECTOMY STUDY Unblinding of Participant

Participant ID:
Participant Initials:
Site:
Date: / / / /
RC ID:

Research Coordinator completes this form if the participant needs to be unblinded	d.
Photocopies of this form with signatures must be faxed to the DCC.	

1.	Date participant was unblinded:	$\overline{M} \overline{M} / \overline{D} \overline{D} / \overline{Y} \overline{Y} \overline{Y} \overline{Y} \overline{Y}$
2.	What was the participant's randomization arm?	 Larly Adenotonsillectomy (EAT) Watchful Waiting with Supportive Care (WWSC)
3.	Why was the participant unblinded?	 Neuropsychological scores fell outside the accepted range Participant experienced an SAE related to medical intervention Parent or child inadvertently disclosed their treatment arm Other, specify:
4.	Was the DCC contacted within 24 hours of unblinding?	□ ₀ No □ ₁ Yes
	4a. If YES, name of the person contacted:	
	4b. If <i>NO</i> , state the reason why:	

PI Signature:	Date:		/	!		/			
0		М	М	D	D	Υ ⁻	Y	Y	Y

Directions: Fax this form to the DCC at (215) 573-6262

C H A T	CHILDHOOD ADENOTONSILLECTOMY STUDY Beery VMI Visit	Participant ID: Participant Initials: Site: Date: / / NP ID:
1.	Was the Beery VMI performed?	□₀ No □₁ Yes
2.	Please indicate the neuropsychological battery performed:	\square_1 Version 1 \square_2 Version 2
3.	Please indicate the child's hand preference:	$ \Box_1 \operatorname{Right}_2 \operatorname{Left}_3 \operatorname{Alternated} \operatorname{Hands} $

Please provide the summary scores from the Beery VMI

		Beery VMI
4.	Raw Score:	
5.	Standard Score:	
6.	Percentile:	

С	CHILDHOOD ADENOTONSILLECTOMY STUDY	Participant ID:
Н	WRAML-2	Participant Initials:
Α	Visit	Site:
Т		Date: / / /
		NP ID:

1. Were any of the sections of the WRAML	-2 administered?
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)	No
Π.	1	Yes

Please provide the summary data from the WRAML2

		Raw Score	Scaled Score
2.	Verbal Learning:		
3.	Verbal Learning Recall:		
4.	Verbal Learning Recognition:		