COVER PAGE

Text2Breathe: Enhance Parent Communication to Reduce Pediatric Asthma Disparities (T2B)

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Text2Breathe: Enhance Parent Communication to Reduce Pediatric Asthma Disparities

PROTOCOL NO.: None
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SPONSOR: National Institutes of Health

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A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat your child.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

More kids who live in cities and low-income neighborhoods have illnesses, like asthma. The National Asthma Education Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma recommend a partnership between healthcare providers and patients (and their parents, for children). This study will try to create a partnership between you and your child's nurse or doctor. We will try to do this by helping parents or guardians have better talks with their child's nurse or doctor. This doctor or nurse is the person in charge of your child's regular medical care. We think better conversations with this doctor or nurse will help make children's asthma better.

You qualify for this study because your child:

- Is 2 to 12 years of age
- Has Medicaid insurance
- Has been diagnosed with asthma for 12 months or longer
- Has come to Seattle Children's or Mary Bridge Emergency Department for asthma care.

PROCEDURES

Today I will ask questions about your child's health, medication use, visits to his or her doctor, visits to the hospital, and how you feel talking with your child's doctor. This will take 30-40 minutes. Because we may be interrupted by providers while I am asking you questions, it is possible it will take longer than 40 minutes in total. We will then divide the study participants into 2 groups. The groups are divided randomly, like flipping a coin. Everyone has the same chance of being in either group. Both groups of parents will get the same care that all families receive at Seattle Children's Hospital or Mary Bridge Children's, whichever you have come to today for care.

One half of the parents (the control group) will get this "usual care." The other half of the parents (the study group) will be in the Text2Breathe text messaging group. The Text2Breathe group will get extra education about how to communicate with your child's healthcare provider. All participants will get a welcome text, reminders about the flu shot and telling you it is time for your phone interview.

If you are in the "study" group, today I will spend about 10-20 minutes talking to you about ways to better communicate with your child's primary care provider about his/her asthma. Also, if you are in the "study" group the Text2Breathe program will send you text messages 2 times a week for 3 months. After 3 months you may text Text2Breathe as often as you'd like to get more information. We will also send you reminders. For example, about the flu shot or following-up with your child's doctor. These texts will be messages about how to talk with your child's primary health care provider about asthma, reminders about what to ask your provider about asthma, and reminders about how to control and treat your child's asthma. The Text2Breathe program is the "experimental" part of the study. We think that children whose parents use the program will be healthier with respect to their asthma.

If you agree to be in the study, we will ask you questions about your child's asthma at 4 specific times:

1. Today
2. 3 months from today
3. 6 months from today
4. 12 months from today

This will happen for participants in both groups. Each interview after today will happen by telephone. All of these interviews will be done by the study staff at the Seattle Children's site. In some cases this interview may happen through a secure website. You will receive a reminder text for each interview appointment. You will also be contacted by study staff at the Seattle Children's site to schedule your interview appointment. Interviews will take 20-30 minutes. We will ask questions about your child's health, medication use, visits to his or her doctor, visits to the hospital, and how comfortable you feel communicating with your child's doctor. After each interview we will look at your child's medical records at the site where he or she was enrolled to check the information you give us about your child's asthma care.

RISKS AND DISCOMFORTS

If you participate in this study there will be no physical or medical risks to you or your child.

Text messaging is an activity in this study. These study text messages could have personal information. This personal information could be seen by someone outside of the study if he or she can see your text messages.

There may be the risk that the study activity may change how you talk with your child's doctor or nurse. The study activities are designed to help you have better talks and get better care. It is possible this change in how you talk to your child's doctor or nurse could be negative to your relationship with your child's doctor or nurse.

The information we will collect for this study is important. We will try to keep you and your family's personal information private. Some information we will collect for the study will be labeled with your name. An example is a report from a laboratory. Another is information about your child's medical history. Information that could identify you or your child will be stored in a locked file cabinet or on secured access computer. Only members of the Seattle Children's and MultiCare research teams will have access to the files.

To protect your information, it will be labeled with a unique number. We will not use your name, or anything else that identifies you, in any publications or talks that might result from this study. Only the study staff will be able to connect you to the unique number.

Like all research, there may be risks that are unknown or unexpected. Please ask the research team your questions about possible risks to you from taking part in this research.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
We do not know if participating in this study will benefit you or your child. If you are in the study group, you and your child may benefit from extra education about how to talk with your child's nurse or doctor about asthma. Better talks with your child's nurse or doctor may have the benefit of better care for your child. The researchers may learn more about asthma. Learning more about asthma may benefit others with asthma in the future.

COSTS

If you join the study, costs to you would include your usual insurance deductibles and co-payments. All of your insurance company's usual rules would apply.

Be aware that standard data fees and text messaging rates may apply based on your plan with your mobile phone carrier.

PAYMENT FOR PARTICIPATION
To thank you for your time we will give you a gift card when you complete each interview. You must complete the interview to receive each payment. Before you leave today we will give you the gift card for the baseline survey you already completed. Money will be added to this card each time after you complete the 3, 6, and 12 surveys.

Interview	Gift Card Amount
Baseline	$20
Three Month Follow-up	$30
Six Month Follow-up	$30
12 Month Follow-up	$30
	Total $110

The payments you receive for being in this study are taxable income. Seattle Children's is required to report to the IRS study payments of $600 or more made to anyone in any year. To make this report you will need to provide your name and address.

ALTERNATIVE TO PARTICIPATION
You may choose not to participate in our study. Your care at Seattle Children's will not change in any way if you choose not to participate. Taking part in the study is voluntary, so you and your child are free to stop being a part of the study at any time without anything bad happening.

Confidentiality
If you take part, we will make every effort to keep your information confidential.

We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

If results of this research are published, we would not use information that identifies you.

We would only use your information for research. These are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.
- Sponsors, government agencies or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.
- Agencies or sponsors that may look at study records include:
    - the FDA,
    - Department of Health and Human Services (DHHS) agencies,
    - governmental agencies in other countries, and
    - Western Institutional Review Board® (WIRB®).

We would keep your results until December 31, 2060.

COMPENSATION FOR INJURY
If you are injured as a direct result of this research study, Seattle Children's Hospital will provide treatment, or will refer you for treatment if needed. Neither you nor your insurance company

will be charged for this treatment. This is the only compensation offered for study-related injuries. It is important that you tell the study doctor, if you think that you have been injured as a result of taking part in this study. You can call the study doctor at (206) 987-3454.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, the National Institutes of Health (NIH), will pay for this research study.

QUESTIONS
Contact Tumaini Coker, M.D., M.B.A at 206-884-0559 or Elizabeth Kleine at 206-884-1978 or 206-469-0371 (24 hours) for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date and Time

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date and Time

Ver. 06/13/2014