Consent Form/Parental Permission

Telemedicine Enhanced Asthma Management through the Emergency Department

Principal Investigator: Jill S. Halterman, MD, MPH

This consent form describes a research study, what you and your child may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your child's routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction
You and your child are being asked to participate in this research study because your child has asthma or reactive airway disease (RAD)

This study is being conducted by Dr. Jill Halterman of the University of Rochester's Department of Pediatrics.

Purpose of the Study
Preventive care for children after a visit to the Emergency Department is important in decreasing symptoms, hospitalizations and successive emergency department visits. However, many children in the U.S. and in Rochester who should be receiving follow-up visits after emergency care are not receiving them. This study will look at whether providing preventive care follow-up and optimal guideline based preventive treatment through the use of telemedicine, will improve children's asthma/RAD symptoms after an emergency department visit.

Study Description

If you choose to participate:

- We will ask you to read and sign this consent form to allowing your child to participate in the study.
- This study is for families of children ages 3-12 years. If your child is 8-12 years old, we will also review the study with your child, and he/she will have to provide his/her agreement to be in the study.
- We will ask you to complete a survey about your child's asthma/RAD, asthma/RAD medicines, visits to the doctor, other factors that may influence your child's asthma/RAD and your family's background.
- A member of the research team may collect samples of saliva from your child's mouth using a swab similar to a long q-tip. The purpose of this is to measure your child's cotinine levels, which shows the amount of cigarette smoke your child may have been exposed to. This is important, because smoke exposure makes asthma/RAD symptoms worse. A second saliva sample may be collected 1 year from now.
- We may ask your child to blow into a hand held device (NIOX VERO) to measure the presence of nitric oxide to detect any inflammation in your child's lungs. We may take these measurements again 1 year from now.
- We may also collect your child's height and weight measurements now and 1 year from now.
- Due to COVID-19, we will not be collecting any of these measures at the initial visit. We may ask to collect these measures in the future with your permission.
- At the end of today's survey, your child will be randomly assigned (like flipping a coin) to either receive 1) follow-up asthma/RAD care through telemedicine at school or home (TEAM-ED Group) or 2) a recommendation to follow-up with your child's primary care provider at their office (Usual Care Group). Your child will have an equal chance of being assigned to either group.
    - If your child is assigned to the TEAM-ED Group, the TEAM-ED program will help make sure your child gets follow-up asthma/RAD care through telemedicine visits. Telemedicineallows children to be seen by pediatric medical providers without the need for an in-person visit to the doctor.
    - If your child is assigned to the *Usual Care Group,* a summary report of your child's symptoms will be sent to your child's doctor, and you will be asked to continue managing your child's asthma/RAD medication and treatment with your child's doctor.
    - A further description of each of these groups is provided in the section below.
- The study team will call you approximately 3months, 6months and 9months after today's visit. During the phone calls, a research assistant will ask you questions about your child's asthma/RAD symptoms, use of medicines, and visits to the

doctor. We will provide you with an asthma/RAD symptom diary today to help you keep track of your child's asthma/RAD symptoms.

- The study team may communicate with you through text messages and emails to send you reminders and schedule appointments.
- In 12 months, we may conduct a home visit and/or call you. We will ask you questions about your child's asthma/RAD symptoms and medication use. As COVID-19 precautions allow, we may also collect a sample of your child's saliva and measure your child's lung inflammation by having them breath into a small machine (called the NIOX VERO) during this visit. We will also ask you about your opinions about this asthma/RAD program.
- At the end of the study, we will contact your doctor's office to review your child's medical record. We will collect information from your child's medical records, including asthma/RAD information, medications and other treatments. We may also obtain pharmacy records to obtain additional information about your child's asthma/RAD medications.
- During the study we will also be looking at your child's medical and school records to collect information about their absenteeism, school nurse visits, medication use, and academic performance.
- While the intervention will be conducted during one year, we may follow you and your child for up to 18 months to obtain final survey data.

COVID-19

- **During the COVID-19 or coronavirus pandemic,** the study team will not be collecting saliva samples or have your child blow into devices to measure lung function or inflammation. As COVID precautions allow, we may attempt to collect these measure in the future, at which point we will notify you and request your permission.
- In the event we are unable to obtain consent in the Emergency Department, we may ask you to provide your consent to the study through a secure web link using REDCap (rather than in person). If you are unable to access the web link, we will plan to meet with you briefly at home or another agreed upon location maintaining social distancing and wearing masks to minimize potential exposure to COVID-19.
- We will follow guidelines outlined by the University of Rochester. Please use the following link to learn more about these guidelines: https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers/human-subjects-research.aspx.

Additional Information about the Study Groups

Telemedicine Care Group

If your child is in the TEAM-ED group, we will notify his/her doctor that your child will be participating in the study and will be receiving asthma/RAD follow-up care through the Telemedicine Program. The Telemedicine Program will schedule a telemedicine visit for your child either in the school health office or using a secure

video platform (e.g Zoom) within one week of today's visit. The healthcare provider will review updated symptom and medication information from their office and contact you by telephone to discuss your child's asthma/RAD, determine a treatment plan, and answer any further questions and concerns.

The Telemedicine Program will schedule the telemedicine visit with your child's primary care practice whenever possible. If there is no telemedicine provider at your child's practice (or if the provider is unavailable for the visit), several other local providers are routinely available to perform telemedicine visits. In this case, a summary of the visit will be sent to your child's primary care physician.

Your child will then receive two more asthma/RAD care telemedicine visits during the year to re-assess asthma/RAD symptoms, adjust the treatment plan as necessary, and discuss your questions or concerns. These visits will occur in approximately 6 and 12 weeks. The healthcare provider will contact you to discuss your child's asthma/RAD and any changes in medications that may be recommended.

Usual Care Group

If your child is in the Usual Care Group, your primary care provider will receive a report on your child's asthma/RAD symptoms, but your child will not receive telemedicine visits through the study for asthma/RAD. You will be asked to continue managing your child's asthma/RAD medication and treatment with your child's primary care provider just as you normally would. If your child is not already taking a preventive asthma/RAD medication, you should contact your child's doctor to discuss these medications.

Number of Subjects

We plan to enroll approximately 430 children, ages 3-12 years, to participate in this study over the course of four years. We are also asking the children's caregivers to participate by completing some surveys.

Duration of the Study

If you decide to participate in this study, your child's study activities and follow-up surveys will be completed over the course of one year, and we may follow you for up to 18 months to obtain data.

Risk of Participation

Since this study is designed to help improve preventive care for asthma/RAD after an emergency visit, your child's provider may recommend that your child start a daily preventive asthma/RAD medication. These medications are recommended as the standard of care for children with persistent asthma/RAD. The most frequently reported side effects of these types of medicines are sore throat, hoarseness, a fungal infection of the throat and mouth, and dry mouth. Rinsing the mouth after using this medicine and always using a spacer/holding chamber (if applicable) decreases the risk of these side effects.

Another potential risk of participation in this study is the loss of privacy if the information collected were to be released. You may refuse to answer any questions for any reason and may also choose to withdraw from the study at any time. Only approved project staff will have access to your data.

The researchers are required to report information regarding potential child abuse or neglect reported by you or observed at your home during a visit. The researcher will also report if there is a reasonable suspicion, based on information provided by you or observed during the visit at your home, that you may present a danger of harm to others or that you may harm yourself unless protective measures are taken.

Transmitting your information by e-mail and/or text messaging has a number of risks that you should consider. These include, but are not limited to, the following:

- E-mail and text messages can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- E-mail senders can easily misaddress an e-mail, and text message senders can easily send messages to the wrong telephone number.
- Backup copies of e-mail and text messages may exist even after the sender or the recipient has deleted his/her copy.
- Employers and on-line services have a right to inspect e-mail and text messages transmitted through their systems.
- E-mail and text messages can be intercepted, altered, forwarded, and/or used without authorization or detection.
- E-mail can be used to introduce viruses into computer systems.

You will be responsible for any additional data usage and/or costs associated with sending and/or receiving text messages and e-mail.

Benefits of Participation

Your child might not benefit from being in this research study. The potential benefit to your child from being in this study might be that children who participate in the TEAM-ED Group may benefit from the additional care that they receive through this study. However, being in the TEAM-ED Group may not give additional benefit above the Usual Care Group. Children managed in studies that help their doctor provide usual care (like the Usual Care Group in this study) may also have better control of their asthma/RAD. The caregiver may not benefit from completing the surveys.

Costs

For children in either group, a follow-up health care visit is recommended since your child is visiting the emergency department for an asthma/RAD exacerbation. Sometimes insurance requires families to pay a co-pay for these visits. If a provider recommends asthma/RAD medications, families may be asked to pay part or all of the cost for these medications.

If your child is in the TEAM-ED Group, your child will receive follow-up asthma/RAD care visits through the Telemedicine Program. The telemedicine provider may prescribe a daily preventive asthma/RAD medication. Similar to an in-person visit, your child's insurance will be billed for the cost of the telemedicine visits, medications and supplies (spacer, tubing, etc.), if needed. If your child does not have insurance, the study team will help you obtain health insurance for your child. If there is no insurance reimbursement for the telemedicine visit, you will not be asked to pay any additional costs for the telemedicine visits. If your child is unable to obtain health insurance or you are unable to pay the co-pay, the study team will assist with the cost of recommended asthma/RAD medications prescribed through the Telemedicine Program during the year. Additionally, you may be charged for using data on your device in accordance with your personal phone plan and rates.

Sponsor Support
The University of Rochester is receiving payment from the National Institutes of Health, including the National Heart, Lung, and Blood Institute for conducting this research.

Payment
Each subject in the program will be paid $25.00 after the completion of the initial survey, $20.00 after each telephone follow-up survey, and $50.00 at the final visit assessment. The payments will be in the form of gift cards.

Compensation for Injury
If your child is directly injured by the clinical procedures solely required to participate in this study, you may need to pay for treatment of their injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research injury will be made on a case-by-case basis.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you/your child private. In order to do so, we will store documents in a secure manner and restrict access to study personnel. Sometimes, however, researchers need to share information that may identify you/your child with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your/your child's personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your child's study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about you/your child?

- The study doctor and the study staff
- URMC and Affiliates

Your/Your child's information may be given to:

- The Department of Health and Human Services;
- The National Institutes of Health;
- The University of Rochester;
- Johns Hopkins University;
- University of Arkansas;
- Salimetrics, LLC.

Why will this information be used and/or given to others?

- To do the research,
- To study the results, and
- To see if the research was done right.

If the results of this study are made public, information that identifies you/your child's health information will not be used.

What if I decide not to give permission to use and give out my/my child's health information?
Then you/your child will not be able to be in this research study.

May I review or copy my/my child's information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last at least 5 years.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your/your child's health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your/your child's health information and they will not be able to stay in this study. Information that

has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you/your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my child's health information protected after it has been given to others?
No. There is a risk that you/your child's information will be given to others without your permission.

Voluntary Participation
Participation in this study is voluntary. You are free to not have your child participate or withdraw your child at any time, for any reason. If you do not choose to participate, or you choose to withdraw from the study, you will not risk any present or future care and it will not put in jeopardy any relationships that you or your child has with faculty at the University of Rochester or Strong Hospital. In the event that you do withdraw your child from this study, the information already provided will be kept in a confidential manner.

Contact Persons
For more information concerning this research or if you feel that your child's participation has resulted in any research related injury, emotional or physical discomfort, please contact: Maria Fagnano at 585-275-8220, or the principal investigator, Jill Halterman at 585-275-5798.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642-8315, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Future Contact
We conduct many studies on pediatric asthma and reactive airway disease. We would like to keep your name and contact information for possible future research studies. If we feel that you or your child may be eligible to participate in one of our future research studies we will contact you. At that time you can decide if you want to participate. If you decide to participate you will need to provide consent again. Your decision about whether or not to participate in future studies will not affect your participation in this study.

SIGNATURE/DATES

After reading and discussing the information in this permission form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to your child;
- Other options your child may have instead of being in the study;
- How your child's personal information will be protected;
- What to do if you have problems or questions about this study.

Parental Permission

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my permission for my child to participate in this study. I will receive a signed copy of this form for my records and future reference.

_____ **YES**, I consent for the organizers of this study, or their representatives, to contact me with information about additional studies.

_____ **NO**, I do not consent the organizers of this study, or their representatives to contact me with information about additional studies.

Study Subject: _____ PRINT

Parent/Guardian Name: _____ PRINT

Parent/Guardian's: _____ *Signature*

Date: _____

Person Obtaining Consent

I have read this form to the parent/guardian and/or the parent/guardian has read this form. I will provide the parent/guardian with signed copy of this consent form. An explanation of the research was given and questions from the parent/guardian were solicited and answered to the parent/guardian's satisfaction. In my judgment, the parent/guardian has demonstrated comprehension of the information.

_____ PRINT Name and Title

_____ *Signature*

_____ Date

Authorization for Release of Medical Information

Patient Name: _____DOB: _____
(MM/DD/YYYY)

Parent/Caregiver's Name: _____

Name of Child's Doctor:_____

OR Name of the Child's Practice: _____

Phone Number of Child's Doctor or Practice (if known):

(585) - ___ ___ ___ - ___ ___ ___ ___

My permission is hereby granted for release of confidential medical information and reports on my child from their primary care provider. I give my permission for the release of this information to *Telemedicine Enhanced Asthma Management through the Emergency Department* at the University of Rochester. I give this release provided that the material exchanged will be kept confidential and used only for the purposes of *Telemedicine Enhanced Asthma Management through the Emergency Department.*

Information on patient _____ is hereby released to:
(print child's name)

Telemedicine Enhanced Asthma Management through the Emergency Department
Children's Hospital at Strong
601 Elmwood Avenue
Rochester, NY 14642

Parent/Caregiver's *Signature*: _____

Date: _____

PLEASE KEEP TOGETHER WITH CONSENT FORM