University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Parental permission form

Title of research study: Efficacy of single vs. double dose dexamethasone treatment for mild to moderate asthma in a pediatric Emergency Department

Version Date: November 7, 2017

Investigator: Dr. Heather Territo

Why is my child being invited to take part in a research study?

Your child is being invited to take part in this research study because he/she has mild to moderate asthma and will be treated with steroids in our emergency department.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not your child takes part is up to you.
- You can choose not to let your child take part.
- You can agree to let your child take part and later change your mind.
- Your decision will not be held against you or your child.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt your child, talk to the research team at 716-323-0221. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu.

if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your child's rights as a participant in this research.
- You want to get information or provide input about this research.

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Why is this research being done?

Asthma affects millions of adults and children every year and accounts for one of the most common emergency room visits during the winter months. One of the ways we treat asthma is with steroids. We usually use Prednisone or Prednisolone to treat asthma as an outpatient, but these medications do not taste good and can cause vomiting, trouble sleeping and behavior changes. These medications also have to be taken twice a day for several days and it can be hard to remember to take them.

This study is designed to look at a different steroid medication called dexamethasone which has been used in asthma treatment in other studies as well as in many pediatric clinics including this emergency department. Dexamethasone is approved by the Food and Drug Administration to treat other breathing problems. It does not taste as bad and may have fewer side effects when compared to prednisone. Dexamethasone does not need to be taken as much as the prednisone, which makes this medication easier to take. By doing this study, we would like to know if one dose of dexamethasone works the same as two doses of dexamethasone in treating children with mild or moderate asthma symptoms. If this is true, then one dose of dexamethasone would increase compliance and could potentially decrease the incidence of side effects.

How long will the research last?

We expect that your child will be in this research study for 6 days, and on the 6th day post ED discharge, we will call you on the phone to follow-up with you about your child's asthma control status. Your child will not be staying longer in the ED due to his/her participation in this study. We will ask you to document your child's asthma status at home for five days after being discharged from our ED, so your child will be in the study for a total of 7 days including the ED visit day and the phone follow-up day.

How many people will be studied?

We expect about 300 people will be enrolled in this research study.

What happens if I say yes, I want my child to be in this research?

If you decide to allow your child to take part in this research study, your child will receive the standard asthma treatment with albuterol or other medications as decided by the ED doctor. In addition, your child will also be treated with dexamethasone for the study purpose. We have two study groups; neither you nor the study doctor will choose which study group your child will be in. Your child will have an equal opportunity (like tossing a coin) to be enrolled into one of the two study groups.

If your child is enrolled into the first study group, he/she will be given one dose of dexamethasone in the ED by our nurse. If your child is enrolled in the second study group, we will give him/her two doses of dexamethasone. The first dose will be given in the ED by our nurse, and the second dose will be given to your child by the care giver 24 hours after the first dose is being given. We will prescribe the second dose of dexamethasone. You can fill the prescription either in our outpatient pharmacy or at

the Walgreens Pharmacy located at 650 Delaware Ave, Buffalo, NY 14202, or a local pharmacy nearby your home.

After ED discharge, your child will continue his/her routine asthma care at home including albuterol and controller medications if he/she has been prescribed these before. If your child is older than 6 years of age, we will also measure his/her peak flow in the emergency department, and our respiratory therapist will provide you a peak flow meter to use at home if your child does not have one. We will ask you to record your child's peak flows every day for five days. We will also ask you to record the results in an asthma score sheet every day in order to monitor your child's asthma symptoms. The asthma score sheet will be provided to you in the ED.

A research assistant will call you on the 6th day after your child's ED visit and get the asthma score information from you. In addition, we would also like to know if you have noticed that your child has experienced any side effects from the medication and if your child has to seek any further medical care after he/she is discharged from our ED. The phone call takes about 5 minutes of your time.

We will not collect any specimen from your child by participating in this study. If your child vomits dexamethasone two times in the ED, he/she will be withdrawn from the study, and our ED doctor will administer IV solumedrol (another steroid) to your child, which is the standard asthma treatment in the ED for children who vomit the oral steroid medication. The study procedure will be ended upon the completion of the phone follow up. We will not contact you for any other study in the future. All data collected for this study will only be used for this research project, and will not be used for future research; the data forms will be kept in a locked file cabinet in our ED research office.

What are my responsibilities if my child takes part in this research?

If your child takes part in this research, you as the legal guardian will be responsible to: (1) administer the second dose of dexamethasone to your child, or notify other care givers to give this medication to your child if your child is enrolled in the second study group; (2) document your child's peak flow measurements and self-assessment scores for 5 days after the ED discharge; (3) we will call you on the 6th day after the ED discharge and would like to get your help to answer some questions regarding your child's asthma status.

What happens if I do not want my child to be in this research?

If you decide not to let your child participate in this study, your child will receive the standard care for asthma treatment, i.e. receives prednisone or prednisolone (for children who cannot swallow pills) twice daily for 5 days or dexamethasone treatment. The decision will be made by your child's ED physician.

One potential risk for your child to receive the 5 days prednisolone is poor compliance since the medication does not taste good, and it requires 5 days treatment. We do not know if there is a significant benefit for children taking the 5 days prednisone or prednisolone treatment compared with taking one or two doses of dexamethasone.

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What happens if I say yes, but I change my mind later?

Your child can leave the research at any time and it will not be held against you or your child.

If you decide to withdraw your child from the study before your child is enrolled in the study, your child will be given the standard asthma treatment as described above. No research data will be collected from your child's medical record.

If you decide to withdraw your child from the study after he/she gets enrolled in the study, but before we conduct phone follow up, we will not call you and collect the follow-up data. Data collected before your withdrawal will continue to be used for this study.

If you withdraw your child from the study when we conduct the phone follow-up, we will collect no more data from your child, but data collected before your withdrawal will continue to be used for the study.

Is there any way being in this study could be bad for my child?

This study involves no more than minimum risk to the participants; there is a risk that your child may not tolerate dexamethasone. If your child throws up two doses of the medication, he/she will be withdrawn from the study. The other potential risk is that your child may continue to have asthma symptoms, but this could happen when your child receives the prednisone treatment as well. If your child's condition is not becoming better or getting worse after ED discharge or finishing his/her second doses of dexamethasone at home, we suggest that you contact your child's primary doctor immediately for further medical care.

The medication used in the study is not a new medication and is used by many pediatric ED doctors to treat asthma in this country including this emergency department. It also has been used to treat other breathing problems like croup.

If your child is pregnant or becomes pregnant during this study, you should be aware that, the study drug is in the same pregnancy risk category (level of risk to the baby) as the drug that is typically used to treat mild to moderate asthma. However, there may be unforeseen risks to the fetus.

Will being in this study help my child in any way?

We cannot promise any benefits to your child or others by taking part in this research. However, possible benefits include that your child may experience fewer side effects from the dexamethasone compared with prednisone he/she would normally receive. In addition, your child will receive one or two doses of dexamethasone treatment, which may lead to a much higher compliance rate comparing the standard 5 days twice daily prednisolone/ prednisone treatment. At the end, his/her participation in this study will help our doctors to find out if we can treat asthma with one dose of dexamethasone with the same effectiveness as the two doses of dexamethasone in the future, which implies less medication and potentially fewer side effects.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization.

We may publish the results of this research. However, we will keep your child's name and other identifying information confidential, only group data will be presented.

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without my OK?

The principal investigator of the study can remove your child from the research study without your approval. Possible reasons for removal include if your child vomits dexamethasone two times in the ED.

What else do I need to know?

You will not be informed of the results of the study. The study results may be presented at a national conference or published in a medical journal. However, only group data will be presented. No individual information or identity will be presented in the public.

Taking part in this research study will not add extra costs to you. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You will pay for the dexamethasone medication your child receives in the ED as well as the second dose of dexamethasone that he/she will receive if your child is enrolled in the second group of the study. You will also pay for the flow meter that the respiratory therapist provides to you in the ED, since it is part of the standard care device for asthma patient. You make the payment for the dexamethasone and the flow meter the same way as you would pay if your child is not taking part in the study.

You or your child will not be paid by taking part in this study.

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Permission to Take Part in a Human Research Study

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about his/her health that will be obtained by the researchers when your child takes participate in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

___X__ Information from your child's full medical records:

___X__ New Health information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

Provide a general description of information that will be collected: Your child's demographic information, current medications, physical exams findings, asthma severity score, patient self-assessment score, ED treatment etc.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

___√__ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to his/her treatment

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All

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reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about your child.

__√__ d. Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Dr. Heather Territo
Division of Emergency Medicine
Conventus Building, 5th floor, Room 5272
1001 Main Street
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your child's individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which your child is otherwise entitled. If you decide not to sign this authorization, your child will not be able to participate in the research study.

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Permission to Take Part in a Human Research Study

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

❑ ❑

Assent

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained Verbally

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent

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