Informed Consent Form

Symptom Clusters in Children with Exacerbation-prone Asthma

IRB Approval Date: October 16, 2024

NCT04002362

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 173 people who are being studied at Emory and Children's Healthcare of Atlanta.

Why is this study being done?

This study is being done to answer the question: Can future asthma exacerbations be predicted in children and adolescents ages 6 up to 21 years with exacerbation-prone asthma? You are being asked to be in this research study because you are between 6 and 21 years old, have been diagnosed with asthma by a physician, and have had at least one asthma exacerbation in the past 12 months.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 48 weeks: 5 study visits. The researchers will ask you to do the following: Receive one triamcinolone injection (visit 1), answer questionnaires, perform breathing tests (spirometry with oscillometry, bronchodilator reversibility, and exhaled nitric oxide), provide blood samples (visits 1, 2, and 5), and provide sputum samples (ages 12+ at visits 1, 2, and 5). All of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Potential benefits from participation include intensive education and support for the management of asthma (including identification of triggers and symptoms) and repeated assessment of asthma control.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The drug that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include side effects from the triamcinolone injection, albuterol sulfate, blood draws, breathing tests, and sputum induction (with 3% saline).

There is also a risk of loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
Since you will receive only one injection of a corticosteroid hormone for treatment, you should also continue your regular doctor’s treatment for your asthma. Another alternative is to not participate in this study and continue to follow your regular doctor’s treatment for your asthma.

Costs
You will not have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

48-week cohort study with 5 study visits

Title: **Symptom clusters in children with exacerbation-prone asthma**

Principal Investigator: Anne M. Fitzpatrick, Ph.D.

Sponsor: National Institutes of Health, National Institute of Nursing Research

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** 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 you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
Children and adolescents with asthma have very different outcomes. Some children do well and have no exacerbations (referred to as asthma "attacks"). Other children have frequent asthma attacks, despite receiving the same treatment. The purpose of this study is to characterize asthma features as best as we can in children and adolescents with exacerbation-prone asthma. We will then see if there are certain symptoms, breathing features, or markers of inflammation in the blood or airway that distinguish children with exacerbation-prone asthma. We will also see if treatment responsiveness and future asthma-related quality of life can be predicted in children and adolescents ages 6 up to 21 years with exacerbation-prone asthma.

What will I be asked to do?
You will be asked to be in the study for 48 weeks. There are 5 visits for this study. You will be asked to answer questionnaires, perform breathing tests (spirometry with oscillometry, bronchodilator reversibility, and exhaled nitric oxide), provide blood samples (visits 1, 2, and 5), and provide sputum samples (ages 12+ at visits 1, 2, and 5). You will also receive an injection of a steroid called triamcinolone at the end of the first visit.

Procedures at the initial visit, Study Visit 1, study week 0

1. Provide Informed Consent for the study. You will review this document and provide your signature if you agree.
2. Undergo a brief physical examination (by RN) including measurement of your height and weight.
3. Medical history review. We will ask you questions about your asthma and the medications that you take.
4. Urine pregnancy testing. If you are a female of child-bearing potential, we will administer a urine pregnancy test.
5. Questionnaires about your asthma and your symptoms. You will complete several questionnaires about your asthma and your asthma symptoms.
6. Perform exhaled nitric oxide testing. This test involves blowing into a small device at a constant flow rate to measure nitric oxide in your breath.
7. Perform spirometry before and after administration of albuterol. Spirometry is a test that measures the amount of air in your lungs. You will exhale forcefully into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.
8. Perform oscillometry before and after administration of albuterol. Oscillometry is a test that measures the amount of resistance in your airways. You will breathe regularly into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.
9. Submit blood samples. You will undergo venipuncture for blood collection. This involves inserting a needle into your vein to collect the blood. Blood will be sent to the laboratory at Children's Healthcare of Atlanta for measurement of things you are allergic to, IgE (protein associated with allergies), and a blood count. Your blood will also be sent to the laboratory of Dr. Anne Fitzpatrick for measurement of inflammation in your plasma and cells.
10. Perform sputum induction if you are 12 years of age or older. This test involves inhaling a salty solution (3% saline) for up to 12 minutes after we give you 4 puffs of albuterol. We will ask you to cough into a cup every 2 minutes.
11. Receive triamcinolone acetonide injection. You will receive an injection of triamcinolone acetonide, which is a steroid medicine that reduces inflammation in the body. This medicine is administered only one time in your gluteal muscle.

Procedures at Study Visit 2, study week 2-3

1. Undergo a brief physical examination (by RN) including measurement of your height and weight.
2. Medical history review. We will ask you questions about your asthma and the medications that you take.
3. Urine pregnancy testing. If you are a female of child-bearing potential, we will administer a urine pregnancy test.
4. Questionnaires about your asthma and your symptoms. You will complete several questionnaires about your asthma and your asthma symptoms.
5. Perform exhaled nitric oxide testing. This test involves blowing into a small device at a constant flow rate to measure nitric oxide in your breath.
6. Perform spirometry before and after administration of albuterol. Spirometry is a test that measures the amount of air in your lungs. You will exhale forcefully into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.
7. Perform oscillometry before and after administration of albuterol. Oscillometry is a test that measures the amount of resistance in your airways. You will breathe regularly into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.
8. Submit blood samples. You will undergo venipuncture for blood collection. This involves inserting a needle into your vein to collect the blood. Blood will be sent to the laboratory at Children's Healthcare of Atlanta for measurement of things you are allergic to, IgE (protein associated with allergies), and a blood count. Your blood

will also be sent to the laboratory of Dr. Anne Fitzpatrick for measurement of inflammation in your plasma and cells.

9. Perform sputum induction if you are 12 years of age or older. This test involves inhaling a salty solution (3% saline) for up to 12 minutes after we give you 4 puffs of albuterol. We will ask you to cough into a cup every 2 minutes.

Procedures at Study Visits 3 and 4, study week 16-20 and week 32-36

1. Undergo a brief physical examination (by RN) including measurement of your height and weight.
2. Medical history review. We will ask you questions about your asthma and the medications that you take.
3. Urine pregnancy testing. If you are a female of child-bearing potential, we will administer a urine pregnancy test.
4. Questionnaires about your asthma and your symptoms. You will complete several questionnaires about your asthma and your asthma symptoms.
5. Perform exhaled nitric oxide testing. This test involves blowing into a small device at a constant flow rate to measure nitric oxide in your breath.
6. Perform spirometry.* Spirometry is a test that measures the amount of air in your lungs. You will exhale forcefully into a mouthpiece.
7. Perform oscillometry.* Oscillometry is a test that measures the amount of resistance in your airways. You will breathe regularly into a mouthpiece.

*Procedure will not be performed if the visit occurs by telephone.

Procedures at the final Study Visit (Visit 5), study week 48-52

1. Undergo a brief physical examination (by RN) including measurement of your height and weight.
2. Medical history review. We will ask you questions about your asthma and the medications that you take.
3. Urine pregnancy testing. If you are a female of child-bearing potential, we will administer a urine pregnancy test.
4. Questionnaires about your asthma and your symptoms. You will complete several questionnaires about your asthma and your asthma symptoms.
5. Perform exhaled nitric oxide testing. This test involves blowing into a small device at a constant flow rate to measure nitric oxide in your breath.
6. Perform spirometry before and after administration of albuterol.* Spirometry is a test that measures the amount of air in your lungs. You will exhale forcefully into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.
7. Perform oscillometry before and after administration of albuterol.* Oscillometry is a test that measures the amount of resistance in your airways. You will breathe regularly into a mouthpiece. We will then give you 4 puffs of albuterol which is a bronchodilator medicine that opens up your airways. The test will be repeated 10-15 minutes after you inhale the albuterol.

*Procedure will not be performed if the visit occurs by telephone.

How will my medicine be provided?

The medicine that you will take for this study will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that

were already collected may be still be used for this study. If you wish to withdraw your permission for your child's samples to be used for this research study, please contact Anne Fitzpatrick in writing at 2015 Uppergate Dr. Suite 326, Atlanta, GA 30322.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

Albuterol: Common side effects of albuterol include increased heart rate and blood pressure, nausea, headache, or anxiety/nervousness.

Sputum induction (3% saline): Side effects of 3% saline can including coughing and throat irritation/burning. These symptoms usually go away within an hour after administration.

Breathing tests may make your child feel dizzy. This will go away when the test stops.

The less common risks and discomforts expected in this study are:

Blood samples: there may be pain from the skin puncture, as well as bleeding or bruising of the skin. There is a rare risk for infection at the place of puncture of the skin.

Rare but possible risks include:

Triamcinolone acetonide injection: Although it has been demonstrated to be safe and is FDA-approved for the age group, repeated dose of triamcinolone can cause hypothalamic-pituitary axis suppression, posterior subcapsular cataracts, decreased bone formation, and increased bone resorption. However, these risks are highly unlikely in this study because it requires only a single administration.

Urine pregnancy testing: If you are a woman: to protect against possible side effects of procedures performed, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a female and can become pregnant you will have a urine pregnancy test up to 5 times during the study. You cannot join or continue in the study if the pregnancy test is positive. The study doctor will inform you of a positive pregnancy test result.

If you are able to get pregnant (that is, you are a female who has begun menstruating and you are not surgically sterile or post-menopausal), you must use birth control during the entire study. Acceptable birth control methods include: abstinence, birth control pills, diaphragm, intra-uterine device (IUD, IUS), Depo-Provera, NuvaRing, birth control patches, single or double barrier methods (condom plus foam/jelly) or surgical sterility.

Physical examination and medical history: there are no risks to these procedures.

Questionnaires may make you feel uncomfortable. You do not have to answer any question if you do not want to.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to see if treatment responsiveness and future asthma exacerbation occurrence can be predicted in children and adolescents age 6 up to 21 years with exacerbation-prone asthma. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

The payment you will receive depends on the types of visits that you complete. If you complete all of the visits in person, you will get $_100_ for Visits 1, 2, and 5, and $_75_ for Visits 3 and 4, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $_450_ total, if you complete all study visits.

If you complete Visits 3, 4 and/or 5 by telephone, you will get $50 for each of those visits.

You will be compensated using "ClinCard", which works like a debit card and is provided by Greenphire. When visits are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. To issue your card, we need to give Greenphire some of your personal information (or your child's). If you do not wish to provide this information, you can still take part in the study, but you will not be paid. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Children's is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep your social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information.

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Total
In-person visit	$100	$100	$75	$75	$100	$450
Telephone visit			$50	$50	$50	$350

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. Since only a one-time injection of a corticosteroid hormone is administered, you must still follow your personal doctor's care for your asthma, whether it be your pediatrician, pulmonologist, urgent care, or emergency doctors.

You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in

this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have an Emory and Children's Healthcare of Atlanta medical record. If you have never been an Emory and Children's Healthcare of Atlanta patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory and Children's Healthcare of Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Children's Healthcare of Atlanta medical record you have now or any time during the study.

Emory and Children's Healthcare of Atlanta may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Children's Healthcare of Atlanta medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Only the results from your complete blood count with differential (CBC w/diff) and specific IgE (allergies) will be place in your Emory and Children's Healthcare of Atlanta medical record.

The results of all other study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

Tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Anne Fitzpatrick at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Children's Healthcare of Atlanta will help you to get medical treatment. Neither Emory, Children's Healthcare of Atlanta nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, Children's Healthcare of Atlanta and the sponsor have not set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Children's Healthcare of Atlanta, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Children's Healthcare of Atlanta employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- Exit questionnaire

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Pregnancy,
- Unwillingness to receive triamcinolone, or
- Planning to relocate before study completion.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.

- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Children's Healthcare of Atlanta may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Institutes of Health, National Institute of Nursing Research is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury due to negligence.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and Children's Healthcare of Atlanta IRBs, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Anne Fitzpatrick, [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Anne Fitzpatrick at [redacted]:

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

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Children's Healthcare of Atlanta of Atlanta and have a question about your rights, please contact Sarah Marie Huban, Director of Clinical Research at [redacted].

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**