

# Children and Teens 3 to 17 Years Old with an Eosinophilic Gastrointestinal Disorder Needed for a Research Study

## Why are we doing this research?

Cincinnati Children's is conducting a research study, sometimes known as a clinical trial or clinical study, to find the best way to define how well a person with an eosinophilic disorder is doing. We also want to see if the way questionnaires are answered can give us an idea of how well the person is doing.

## Who can participate?

Children and teens, 3 to 17 years old, with an eosinophilic gastrointestinal disorder may be eligible for participation.

Eosinophilic gastrointestinal disorders include: eosinophilic esophagitis (EoE), eosinophilic gastritis (EG), or eosinophilic colitis (EC).

## What will happen in the study?

If your child qualifies and you/your child agree to take part in the study, the following may happen during his or her scheduled visit with their regular doctor:

- You/your child will be asked to read and sign a consent form.
- Information about your child's eosinophilic disorder will be entered into a database.
- You/your child will be asked to complete questionnaires about your child and his or her medicines, medical history, test results, quality of life and symptoms (this will take 30 to 45 minutes and can be completed at home or during the visit).

\*\* When we say "your child's regular doctor", we mean your child's doctor who treats his or her eosinophilic disease.

## Standard of Care Endoscopy

During the study your child will continue to receive normal standard of care (SOC) treatment from his or her regular doctor. The research study doctors will not treat your child's eosinophilic disorder, as it will be the choice of your child's regular doctor.

## Optional Research Procedures During SOC

The following is a list of some of the OPTIONAL research procedures that may happen during your child's SOC endoscopy:

- We would like to collect additional samples of blood, for DNA, during your child's SOC endoscopy.
- If you would like to provide DNA, but do not wish for your child to donate blood, he or she may donate saliva instead. Saliva will only be collected if blood is not obtained.

- During your child's SOC endoscopy, we would like for his or her regular doctor to take additional samples of tissue for us to examine and store in a laboratory. We would also like to receive some of the tissue that your child's doctor examines after the biopsy.
- Before your child comes in for the SOC endoscopy, we will need a stool sample collected from your child and brought to the appointment.
- If your child has a follow-up SOC endoscopy while enrolled in the follow-up portion of this study, we would like his or her regular doctor to take additional samples of tissue for us to examine and store in a laboratory. We would also like to receive some of the tissue that your child's doctor examines after the biopsy.

### **Change in Standard of Care Treatment Visits**

If you/your child agree to participate in this part of the study, a member of the study team will contact you to schedule a visit whenever your child's regular doctor makes a change to his or her treatment (for example, a change to diet or medication).

At this visit, you/your child will be asked to complete questionnaires about his or her medical history, medicine(s), tests results, quality of life and symptoms. You/your child can complete the study forms, which will take about 30 to 45 minutes, at home or during the visit.

### **Annual Follow-Up Visit**

If you/your child agree to participate in this part of the study, a member of the study team will call to schedule an annual follow-up visit.

At this visit, you/your child will be asked to complete questionnaires about his or her medical history, medicine(s), tests results, quality of life and symptoms. You/your child can complete the study forms, which will take about 30 to 45 minutes, at home or during the visit.

### **Genetic Tests (DNA)**

The testing we do using the biopsy and stool samples is not a genetic test. However, the optional blood or saliva samples will be stored for future genetic testing. All DNA resulting from blood or saliva samples will be processed and stored at Cincinnati Children's.

Genetic and DNA testing in this study is to find risk factor genes for eosinophilic disease. You will not receive results from this testing.

Parents, legal guardians and/or participants interested in being part of this research will be given a consent form that thoroughly explains all of the details of the study. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

### **What are the good things that can happen from this research?**

Your child will not receive any direct medical benefits from participating in this research study. This study is not designed to treat any illness or to improve your health. However, we hope the

results from this study may help your child and other people with eosinophilic diseases in the future.

**What are the bad things that can happen from this research?**

A detailed list of possible side effects will be provided to those parents, legal guardians and/or participants interested in knowing more about this study.

**Will you/your child be paid to be in this research study?**

Participants will not receive pay for their time, effort and travel for this study.

**Who should I contact for more information?**

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