What you should know about clinical research studies.

Clinical research studies aim to answer specific questions about how medicines work in the volunteers who take them. You should feel fully informed about what to expect from participation in a clinical research study.

Researchers use clinical studies to:
- Answer specific health questions
- Learn about the effects and safety of investigational medications
- Help find new ways of using approved medications

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles. Before a clinical research study can begin, an institutional review board (IRB) or ethics committee (EC) must review and approve the study.

Participation in any clinical research study is completely voluntary, and you or your child may withdraw from a clinical research study at any time for any reason. Before volunteering for a clinical research study, it is important to weigh the potential risks and benefits of participation. The study team will inform you of the potential risks and benefits of study participation, as well as possible side effects. To make an informed decision, gather as much information as possible and talk to your healthcare providers about any questions you may have.

Thank you for considering the ADvocate Studies!
Atopic dermatitis is more than skin deep.
As you know, atopic dermatitis (AD) is a chronic, severe form of eczema that is marked by the appearance of dry, red, and itchy skin. Most commonly, AD affects the cheeks, arms, and legs. There are times when AD can flare up and symptoms worsen, which can lead to more intense itching and more open sores. AD flares are triggered by various skin irritants, stress, temperature changes, sweat, and allergies. But these painful, irritating symptoms just scratch the surface of what it’s like to live with AD. There’s the embarrassment that comes with exposing the red, patchy skin, or the added irritation that comes from wearing long sleeves to cover it up, but you or your child is not alone. Studies show that more than one-third of people with AD say they “often” or “always” feel angry or embarrassed by their appearance due to the condition.

It can be frustrating searching for the right treatment option for you or your child – especially if you’ve tried many and none have worked. However, right now, research is underway on an investigational medication for AD, and you or your child may be able to take part.

About the ADvocate Studies.
We are looking for volunteers ages 12 and older who have moderate to severe atopic dermatitis to participate in these studies. The purpose of the ADvocate Studies is to evaluate the safety and effectiveness of an injectable investigational medication for moderate to severe atopic dermatitis.

Individuals will be evaluated to determine their eligibility to participate. Those who qualify may receive either the investigational medication or a placebo, as well as study-related medical exams and laboratory tests, all at no cost. Compensation for travel may also be available.

Who is eligible?
An eligible participant for these studies must:
• Be an adult or adolescent, 12 years of age or older, and weigh at least 40 kg (88 lb.)
• Have chronic atopic dermatitis for at least one year
• Have a history of inadequate response to topical treatments for atopic dermatitis

What to expect.
Participation in one of the ADvocate Studies may last between 30 and 66 weeks and consists of three parts:
• During a screening period of up to 30 days, the study doctor will perform tests and procedures to determine if you or your child is eligible to participate.
• If eligible, you or your child will enter one of the treatment periods, depending on the study you or your child qualifies for. In one treatment period option, you or your child will be assigned to and begin receiving the investigational medication. In the other, you or your child will be randomly assigned to receive either the investigational medication or a placebo (which contains no active medication). The investigational medication and the placebo are both delivered as injections. Depending on the study you or your child qualifies for, the treatment period may last between 16 and 52 weeks. The study doctor will explain all study requirements and length of participation in greater detail during the screening period.
• You or your child may stop participating by scheduling a safety follow-up visit approximately 12 weeks after the last dose of investigational medication. Or, if at the end of the treatment period you or your child meet certain criteria, you or your child may be eligible to continue receiving the investigational medication in a separate long-term extension study.

Depending on which study you or your child participates in, you and the doctors may or may not know the treatment assignment. For one of the treatment assignments, participants will receive the investigational medication and everyone will know it. For the other, participants will be randomly assigned to receive either the investigational medication or a placebo, and neither the participants nor the study team will know the treatment assignment, but in case of an emergency, the study doctor can quickly find out.

To learn more about study participation and to see if you or your child may qualify, visit ADvocatestudies.com today.

1. nationaleczema.org/research/eczema-facts/