ERIE RETINA RESEARCH

DEDICATED TO DISCOVERY

A Guide for Volunteers in Vision Research Clinical Trials

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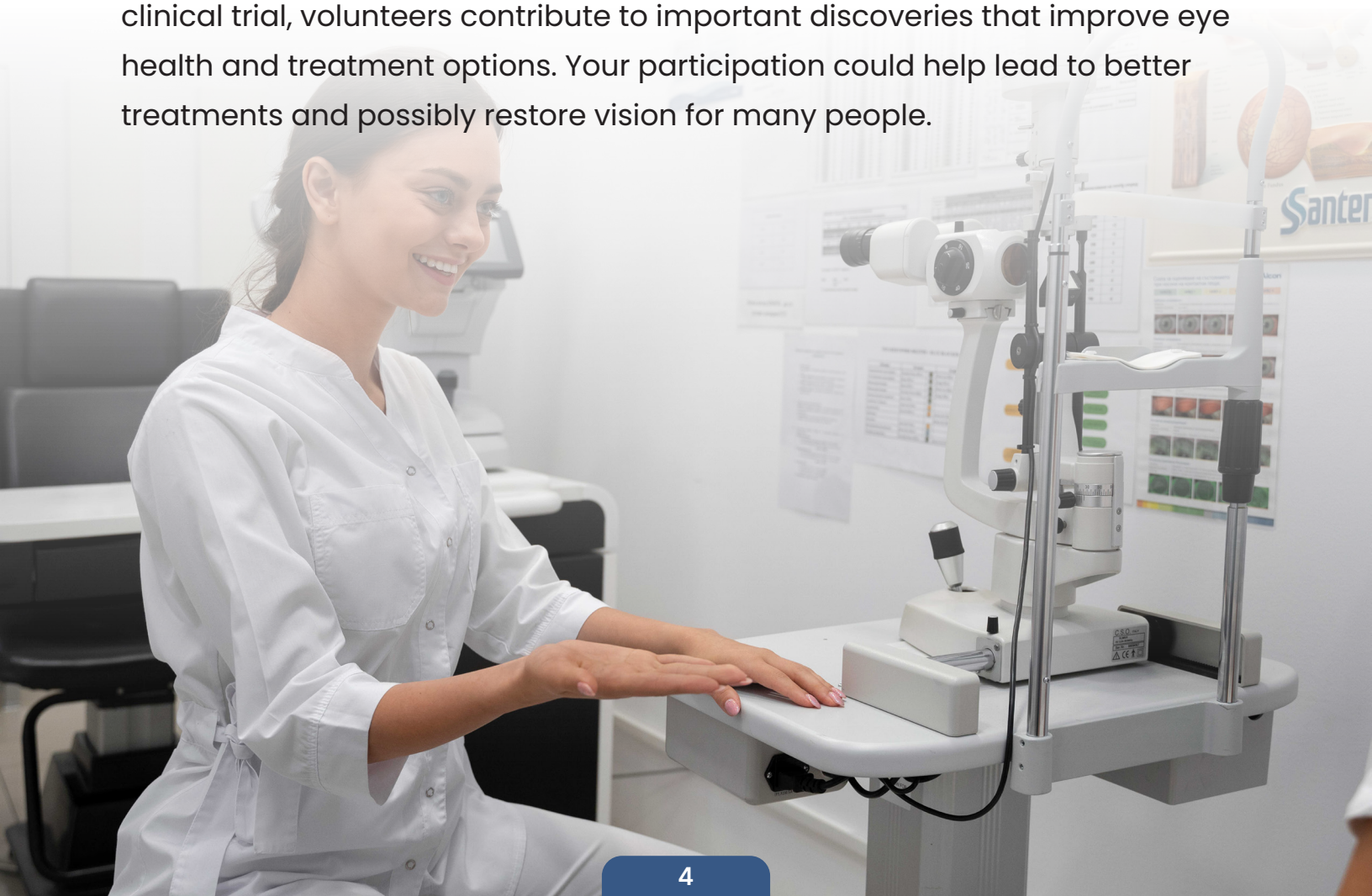
By participating in vision research clinical trials, volunteers contribute to medical advancements that lead to significant improvements in eye health globally.

Join the Vision Research Through Clinical Trials

If you or someone you know is considering joining a clinical trial, this guide will provide the necessary information. Clinical trials in vision research have developed new drugs, surgeries, and detection methods that have greatly improved or saved the vision of millions. Spearheaded by Dr David Almeida, MD, MBA, PhD, Erie Retina Research offers cutting-edge surgical and pharmaceutical ophthalmic research. Our team is fast-paced, energetic, innovative, and proud of our groundbreaking work and practices in Erie, PA. We can help facilitate studies, bring products to market, collaborate on ophthalmology-related research, and more. We bring groundbreaking studies to our community, and we are focused on vision and committed to empowering sight through science. This guide explains how by joining a clinical trial, volunteers contribute to important discoveries that improve eye health and treatment options. Your participation could help lead to better treatments and possibly restore vision for many people.



A clinical trial is research where volunteers test new medical treatments to confirm their safety and effectiveness.

What Should Volunteers Know About Clinical Trials?

What exactly is a clinical trial?

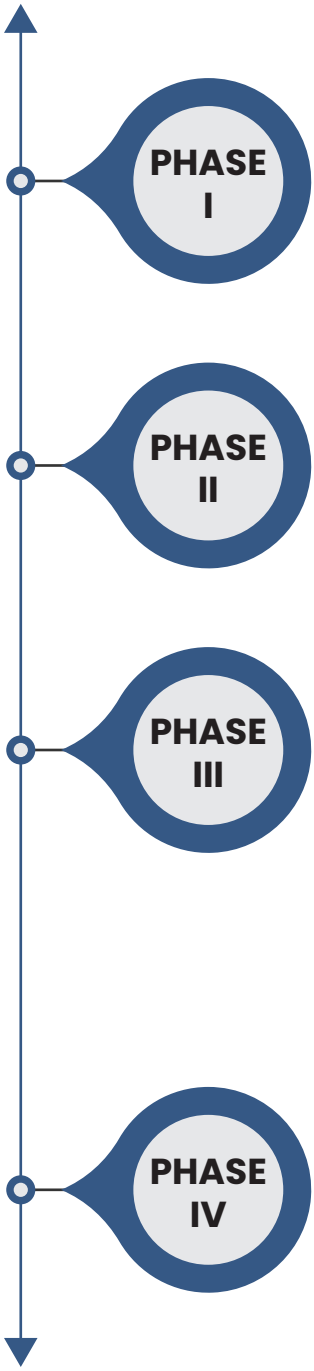
Clinical trials are research studies where volunteers help assess new medical treatments, procedures, or devices aimed at preventing, diagnosing, or treating various health conditions, including eye diseases and disorders. These trials are crucial for determining the safety and effectiveness of these new approaches.

Medical research typically starts in the laboratory where scientists develop and test new treatments. When a treatment looks promising in lab tests, it progresses to clinical trials, which involve human volunteers. This allows researchers to determine whether the treatment is safe and effective for people.

For example, a clinical trial might explore a new medication for treating age-related macular degeneration or test a novel surgical procedure for removing cataracts. These trials are essential for advancing eye care and introducing new therapies to the public.

What are the main phases of clinical trials?

Clinical trials are categorized into several phases, each with a specific purpose:



Clinical trials involve a small group of volunteers and aim to find the safest dose of a new treatment and identify any side effects.

Clinical trials are conducted with a larger group to further examine how the treatment affects the body, the optimal dosage, and its impact on specific eye conditions.

Involves hundreds or thousands of participants and is conducted at multiple locations. In these trials, the new treatment is compared to existing treatments or a placebo to determine its effectiveness and safety. This phase answers the question of whether the new treatment works better or is safer than existing options and is critical for gaining regulatory approval.

Is conducted after a treatment is approved to monitor its long-term effects and gather more comprehensive data on its safety and effectiveness across a broader population.

> Clinical trials employ a controlled format to contrast the therapeutic effects of a new treatment with those of an ongoing treatment.

How does a clinical trial process work?

- A clinical trial is managed by a principal investigator, the lead researcher in charge of the study. A clinic coordinator handles the organization of volunteer visits and provides clear explanations of the trial's processes.
- Volunteers must meet specific eligibility criteria that can include age, the type and stage of an eye condition, and any prior treatments. Those who qualify are required to sign an informed consent form. This document outlines the study's goals, participation criteria, the treatments involved, potential risks and benefits, volunteers' rights, and expectations.
- All doctors involved follow a strict treatment plan, known as the study protocol, to ensure every participant receives the same care.
- Clinical trials are designed to measure the effects of new treatments by comparing them to standard treatments, placebos (substances that look like the medication but have no treatment effect), or sham treatments (procedures that mimic the real treatment but have no therapeutic effect).
- Volunteers are placed into groups randomly, which might include a group receiving the new treatment or a control group that gets the standard treatment, a placebo, or no treatment at all. Using placebes and sham treatments helps to clearly identify the actual benefits and side effects of the new treatment by eliminating psychological or other unrelated effects.
- Random assignment helps ensure fairness in how treatments are distributed, giving each volunteer an equal chance of being in any group. The effectiveness and potential side effects of the treatment are not known to participants during the trial to maintain the study's integrity. In non-masked trials, both volunteers and their doctors know which group they are in. In masked trials, this information is withheld from volunteers, and in double-masked trials, neither the volunteers nor the doctors know. This prevents biases based on expectations from affecting the results.
- Volunteering in a clinical trial significantly contributes to medical research. It can provide early access to new therapies and help improve treatments for future patients with similar conditions.

How are clinical trials in vision different from other clinical trials?

Vision clinical trials are unique because they can treat one eye and use the other as a control. This possibility is especially useful if both eyes are affected by the same condition. Researchers can apply the new treatment to one eye and either no treatment or a placebo to the other. This direct comparison helps accurately determine the treatment's effectiveness.

> **To determine its success, a clinical trial often requires a long-term study of its participants' health outcomes.**

How to participate in a clinical trial?

Expectations for volunteers

When you participate in a clinical trial, you will typically undergo several eye exams and other tests to assess the effectiveness of the treatment. This might include trying a new medication or undergoing a surgical procedure. After initial treatment, you will need to visit the medical facility regularly for follow-up exams. These visits are crucial as they help researchers determine the long-term effectiveness of the treatment.

The follow-up periods can extend for months or even years. It's important to commit to these follow-ups because the trial's success largely depends on collecting long-term data from participants. Without consistent participation in these follow-up exams, the trial results may not be reliable.

Benefits of participation

As a participant in clinical trials, you'll be cared for by a team of expert doctors, nurses, technicians, and support staff. You might be among the first to receive new, potentially effective treatments. If the treatment proves successful, it could improve your vision or prevent eye conditions from developing.

Additionally, if you're in the control group and the treatment is found effective, you could be among the first to benefit from it after the study concludes. By participating, you also contribute to medical research that might benefit others with similar eye conditions and could provide improved care for family members if the condition is hereditary.

Risks

Participating in a clinical trial carries certain risks. It's impossible to predict exactly how well a new treatment will work for you specifically. There may be side effects, some of which could be serious and require medical intervention.

It's important to note that a new treatment might not be more effective than standard treatments, might not work at all, or could potentially be harmful.

Can volunteers leave a study due to health concerns?

Your health can change unexpectedly during the study, including developing conditions not related to the treatment or your vision. If such a situation arises, the medical team might decide you should exit the study to focus on your overall health, which is always the priority.

How patient safety is ensured in clinical trials?

Before a clinical trial starts, it must be approved by an Institutional Review Board (IRB). This group checks that the trial's design is scientifically valid and prioritizes the safety of the participants. Throughout the trial, doctors monitor participants closely to check how well the treatment works and to spot any side effects.

All findings are documented and reviewed continuously. An independent Data and Safety Monitoring Committee also oversees the trial. This committee of experts reviews data regularly and can stop the trial if it becomes too risky for participants or if the treatment is proven highly effective and should be made available sooner.

What does participating in a clinical trial cost?

If you participate in a clinical trial at Erie Retina Research, there is no charge for any medical care received. Clinical trials at other sites may have associated costs, such as fees for medical procedures that are a part of standard care. These costs might not be covered by your health insurance. Talk to your healthcare provider and insurance company about any potential costs before you decide to participate in a trial.

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You need to know the risks and benefits of the treatment in the clinical trial vision research.

Volunteer Rights in Clinical Trials

Know the following rights of volunteers in clinical trials to make informed decisions and participate confidently:

- Understand all the potential risks and benefits associated with the treatment being studied.
- Know the specifics of how, when, and where the researchers intend to conduct the study.
- Be informed about your role and responsibilities within the study.
- Be aware of any financial obligations, including costs for you or your insurance.
- Know if any of your medical or personal information will be shared with other researchers involved in the study.
- Have open and honest communication with the medical professionals overseeing the trial.
- Feel comfortable asking any questions you may have about the study.
- Have the freedom to withdraw from the study at any time, although it's essential to consider this decision carefully before enrolling.
- Receive updates on any new information regarding the treatment throughout the study.
- Be notified of your treatment assignment once the study concludes.
- Have your privacy protected even after your participation ends, ensuring your name is not disclosed in any study-related reports.

Consult your doctor, family, and clinical trial staff to determine if a particular study is suitable for your needs.

What details should a volunteer know before making a decision?

Before committing to a clinical trial, it's important to know its details. Discussing with your healthcare team and loved ones can help you determine if it's the right choice for you. Here are some key questions to clarify before making your final decision:

Understand the study

- Why are researchers doing this clinical?
- Why do researchers think the new treatment might work better than what's currently available?
- What are the known side effects of the treatment?
- What tests and treatments will I undergo?
- Will surgery or medication be required?
- Do I need to stay in the hospital?
- How will participating in the study help me and others?

Assess the impact of a clinical trial on your health:

» What advantages could the treatment offer for my specific eye condition?

» What are the potential negative effects, both immediate and over time, associated with the treatment?

» What are the probabilities of encountering any adverse reactions during the treatment?

» How will my overall health and well-being be tracked and evaluated throughout my participation in the study?

» Who will oversee my medical care during the trial, and will I have the option to consult with my regular physician during the process?

Evaluate your commitment

» How will participation in the trial affect my daily life?

» What's the conducted duration of the treatment?

» How frequently are follow-up appointments required?

» What's the overall time commitment?

» Are there any financial considerations associated with participation?

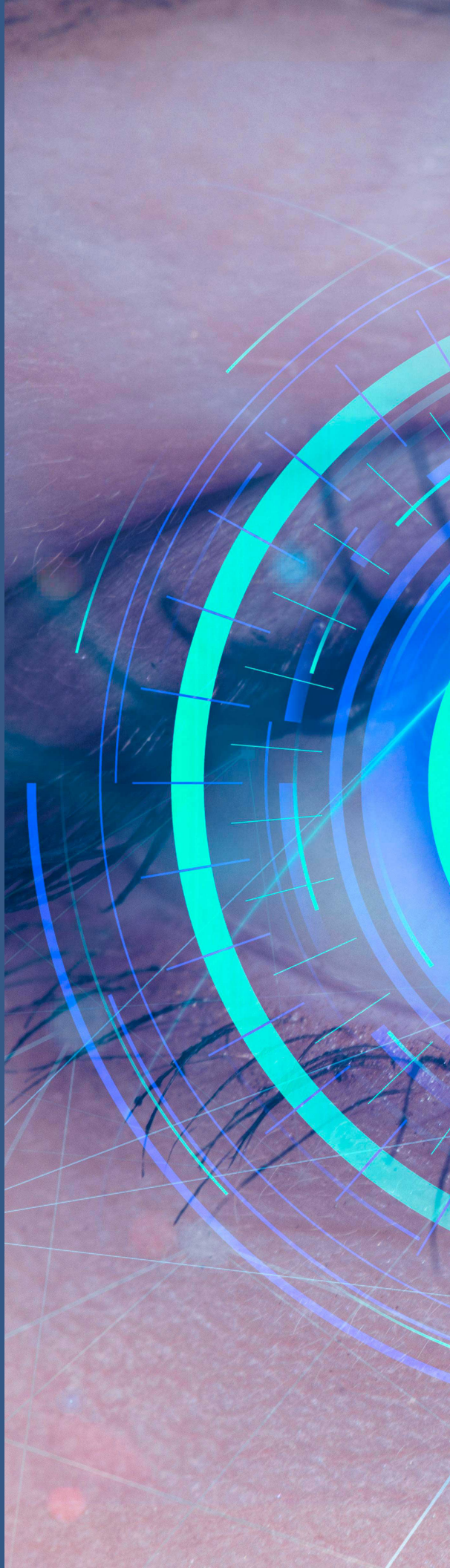
» How do I and those close to me feel about my involvement in the trial?

How can you participate in clinical trials at ERR?

If you're considering joining a clinical trial, you can submit your details for a preliminary screening on Erie Retina Research's website, and a screener will contact you to assess your eligibility.

To learn more about joining an ERR clinical trial, visit:

https://erieretinaresearch.com/



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