

## **TO OUR PATIENTS**

The doctors at the Retinal Consultants are committed to bringing you the most advanced medical and surgical care available. As part of this commitment, we are improving upon current treatments through research. This document explains how we conduct this research and how you may be able to help by participating in a research study if you choose.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the doctors or research staff.

You are being asked to review this information because you may have a condition for which new treatments are being investigated. If you qualify, you may be able to participate in a research study

### **Why are these studies being done?**

Many of the conditions we treat have well-established and effective treatments. Some of these treatments work well, but we are constantly trying to improve upon them. For other conditions, effective treatment is not available. At this practice, we always want to bring you the best care possible, and this includes participating in well-designed research studies to advance medical care.

### **How many people will take part in a study?**

Studies vary in the number of patients that take part. Some studies require only a few dozen patients and others require hundreds or even thousands. Statistical analysis determines the number of patients required to satisfactorily answer a research question. Only a small percentage of our patients qualify and volunteer to participate in research studies. These patients are often combined with other patients from other research centers across the country to achieve the required number of patients to conduct the study.

### **What will happen if I take part in this research study?**

If you agree, you will be carefully screened for your eligibility to participate. This usually involves a careful eye examination and supplemental diagnostic tests. In most cases, these are the same tests that would be required for your care regardless of your participation in a research study. However, because of the demands of research, testing for studies must be done in a standardized way and this may take additional time. In some cases, the interview and examination to determine your eligibility to participate in a research study will occur at a separate visit on a different day than your clinic appointment.

### **How long will I be in the study?**

The length of time you will be asked to participate in the research study will depend on the specific study for which you qualify. Some studies require as little

as a few months of participation while others ask that you participate for over a year. If you agree to participate in a study, we encourage you to remain a participant for the planned duration of the study.

### **Can I stop being in the study?**

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. However, the benefits of the study are greatest when patients participate for the duration of the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

### **What side effects or risks can I expect from being in the study?**

At this practice, we carefully select the studies we run for safety and responsibility. The object of research is to learn and to develop better treatments, and the outcomes of the study are not known at the start. However, we would only participate in research where we feel that the scientific basis is solid. Our goal is to only participate in studies where study participants have the potential to receive more advanced care than is available outside the study. The specific risks or side effects for each study are different and will be discussed in detail with you by one of the research staff before you agree to participate. Often the most significant "side effect" of participating in the study is that you may be asked to have more frequent or longer clinic visits to allow for the study examination and treatments.

### **Are there benefits to taking part in the study?**

In most cases, participation in the study will make you eligible to receive exams and treatments at no cost or a reduced cost to you or your insurance.

Participation in a study may also allow you to receive a new treatment before it is available to the general public. In many cases these treatments are not available to patients who do not participate in the study.

Additionally, study patients are monitored very carefully, often with additional testing that is more than the usual for other patients with similar conditions. This intensive monitoring is provided at no additional cost to you or your insurance.

The greatest benefit of participating in the study may not be to you directly. Previous participants in studies have allowed us to provide the modern treatments we now have available. Your participation as a research subject will benefit future patients with your condition.

### **What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will be treated with the

same high standards of care we offer to all of our patients. The most advanced treatments available outside of research studies will be available and offered to treat you.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

**Will I be paid for taking part in this study?**

You will not be paid for taking part in this study.

**What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and your rights as a patient in our practice remain unchanged.

**Who can answer my questions about the study?**

You can talk to the doctors or the research staff about any questions, comments, or concerns you have about participating in a research study.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in a research study and would like to know if you qualify, please indicate by signing below.

**YES. I HAVE READ THE INFORMATION ABOVE AND AM INTERESTED IN LEARNING ABOUT WHETHER OR NOT I QUALIFY TO PARTICIPATE IN A RESEARCH STUDY.**

**NO. I AM NOT INTERESTED IN PARTICIPATING IN A RESEARCH STUDY AT THIS TIME.**

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Date

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Date