

STUDY: T-REX-DME  
PROTOCOL NO: T-REX-DME  
STERLING IRB ID: 4446-001  
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## **PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION**

**STUDY TITLE:** A phase I/II, open-label, multicenter, randomized, controlled study of the safety, tolerability and efficacy of intravitreal injections of 0.3 mg ranibizumab given monthly compared to a Treat and Extend protocol, with and without laser photocoagulation, in patients with Diabetic Macular Edema (T-REX-DME)

**PROTOCOL NO:** T-REX-DME

**STUDY DOCTOR:** John F Payne MD

**STUDY SITE:** Palmetto Retina Center  
124 Sunset Court West  
Columbia, SC 29169

**TELEPHONE:** 803-931-0077 (24 hours)

**SPONSOR:** Palmetto Retina Center

You are being asked to participate in a medical research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The study doctor or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. This form may contain words that you do not understand. Please ask the study doctor or study staff to explain the words or information that you do not understand. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

### **BACKGROUND**

You are being asked to participate in this study because you have been diagnosed with diabetic macular edema (DME). DME is a type of diabetic retinopathy. Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in American adults. It is caused by changes in the blood vessels of the retina.

Blood vessels damaged by diabetic retinopathy, which can lead to vision loss, can cause fluid to leak into the macula (inside of your eye): the part of the eye where sharp, straight-ahead vision