INFORMED CONSENT FORM
BASCOM PALMER EYE INSTITUTE
University of Miami
CLINICAL INVESTIGATION CONSENT FORM

TITLE:

STOP RETINAL GANGLION CELL DYSFUNCTION STUDY

(STOP-RGCD)

PURPOSE:

You are being asked to participate in a clinical research study to determine if a test, the Pattern Electroretingram (PERG), is useful in predicting which people with known risk factors for developing glaucoma are more likely to actually develop it.

Glaucoma causes progressive death of the cells within the eye that make up the optic nerve, the nerve that carries sight information from the eye to the brain. If glaucoma is present and not treated with eye drops to lower the intraocular pressure (a known risk factor for glaucoma and glaucoma progression), damage to the optic nerve can result in a continuing loss of vision and eventually blindness.

You do not have glaucoma, but have suspicious signs in one on both of your eyes that may indicate that you have the disease at a very early stage or that you are at risk of developing it in the next few years. In this situation it is important to check at regular intervals how much optic nerve fiber tissue is present in your eye and how it is functioning, in order to tell if damage is occurring. This is possible by means of two noninvasive techniques, called Optical Coherence Tomography (OCT) and the pattern electroretinogram (PERG). The OCT yields an image of the thickness of the retina, from which we can evaluate the amount of optic nerve tissue which is present. The PERG is a test of function, and measures the electrical response of the eye when you look at a pattern of moving stripes on a TV monitor. This is a form of stress test for the function of the optic nerve, and may reveal a reduced functional reserve of the cells before a more standard measure of function, the visual field test, becomes abnormal.

We are asking you to participate in a research study which will be monitoring the amount and the function of your optic nerve fibers over the course of four years. In the initial part of the study, we will determine whether or not your PERG test is normal or abnormal. If your PERG result is abnormal, but you have no

abnormality on visual field testing or the OCT test, you will be randomized 1:1 to either take or not take eye drops to reduce the eye pressure for the rest of the study, or until changes in the visual field or OCT occur. This assignment will not be made by the investigator and he will not be aware of whether you are or are not taking drops throughout your participation in the study. If your PERG test is normal, you will be observed without treatment, undergoing visual field and OCT testing each 6 months for 4 years. This will enable the study to determine if the results of PERG testing aid in predicting the chances of developing glaucoma, by comparing those subjects with a normal PERG to those with an abnormal PERG who are not treated, and also if eye drop medication is effective in preventing such change in those with an abnormal PERG test.

This study has been reviewed for its scientific merit and is sponsored by the National Eye Institute of the National Institutes of Health, Bethesda, MD. A total of 500 subjects will participate in this research study.

PROCEDURES:

The PERG is recorded from small metallic buttons taped on the skin similarly to an electrocardiogram, with the difference that the electrodes are around the eyes. The only physical contact you will experience is a gentle cleaning of the skin with an alcohol prep pad and placement of the buttons. During the test you must look with both eyes at a TV display for about 3 minutes. During the follow up period you may be asked to take one more PERG test lying down in a bed. This will cause a momentary increase of your eye pressure similar to the one that occurs during your normal sleep. This may help to understand whether or not your optic nerve functions normally when the pressure in your eye increases.

For OCT evaluation, the pupil has to be dilated with drops as you did before for your eye exam. You have to briefly look at a mark inside the instrument, one eye at a time. PERG and OCT will be performed during the same day of your visit with the eye doctor. If you have already done these tests in the past, as part of another study or as part of your standard treatment, the results of these tests will be obtained from your record, and be included in this study.

If you are a participant in the Observation Group, you will be monitored with PERG, OCT, and standard clinical examinations every six months until the close of the study. If you are a participant in the Medication Group you will be also treated with eye drop medicines.

RISKS:

There are certain risks and discomforts that may be associated with this research. You should be aware that you are at risk of developing glaucoma whether you participate in the study or not. However, being in the study allows you to be followed carefully by standard means of detecting the earliest damage. It is not known whether the risk of developing glaucoma is reduced by eye drops to lower eye pressure in people with risk factors other than elevated eye pressure, and if you have elevated eye pressure your eye doctor has determined that your combination of risk factors is not sufficient to recommend treatment yet. This study is designed to determine if the results of PERG testing aid in the prediction of who will develop glaucoma.

If you are included in the Medication Group, there is a risk of the development of a side effect to one of the prescribed medications:

Prostaglandin analog (include Xalatan®, Lumigan®, and Travatan Z®,) : possible changes in eye color and eyelid skin color, atrophy of fat around the eye (making the eyes less prominent), stinging, blurred vision, eye redness, itching, burning.

Beta blockers such as timolol: low blood pressure, reduced pulse rate, fatigue, shortness of breath, asthma; rarely: reduced libido, depression (all reversible by discontinuation)

Alpha agonists (Alphagan®P, Iopidine®) : burning or stinging, fatigue, headache, drowsiness, dry mouth and nose, relatively higher likelihood of local allergic reaction.

Carbonic anhydrase inhibitors (CAIs) as eye drops (Trusopt®, Azopt™): stinging, burning, eye discomfort.

Combined medications can offer an alternative for patients who need more than one type of medication: side effects may include any of the side effects of the drug types they contain.

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For the PERG, the only significant risk to you is a small chance of a rash to the cleansing agent for skin electrodes, which should go away without treatment. For OCT, there is a rare risk to you of an allergic reaction to the drops used to dilate your pupils. The risk is even lower if you did not have any reaction during your previous eye exams. In case of an allergic reaction, your eye doctor will immediately treat it. If you had previous problems with pupil dilation, you may wish to speak to your eye doctor about the option of doing this test.

BENEFITS:

There is no benefit to you in participating in this study.

COSTS:

PERG testing will be provided at no expense to you. OCT, visual fields, and eye drops medications will be billed to your insurance and, just as for visual fields, may require authorization before OCT is performed. You should be aware that you may be expected to travel and park at your own expense to and from our facility. PERG and OCT testing will be scheduled on the same day as your visit to the doctor.

PAYMENT:

You will not be paid for participating in this study.

ALTERNATIVES:

You have the alternative not to participate in this study.

COMPENSATION FOR INJURY:

Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

CONFIDENTIALITY:

Your consent to participate in this study includes consent for the investigator and her assistants to review all your medical records as may be necessary for the purpose of the study. The investigator and his assistants will consider your records confidential to the extent permitted by law. Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The U.S. Department of Health and Human Services (DHHS) or the Food and Drug Administration (FDA) may request to review and obtain copies of your research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; see below); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects. This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations. It may also be released to your insurance company in order to receive reimbursement for covered services.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including the inclusion of research data in your medical record at the University of Miami. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

UChart Language

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access

to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in UChart. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

INCLUSION OF CERTAIN STUDY TEST AND PROCEDURE RESULTS IN YOUR MEDICAL RECORD

If you are or have been a patient at a University of Miami facility, then you will have a University of Miami medical record. The University of Miami has implemented an electronic medical record system known as UChart, which will improve access to information important to your medical care.

Since this study is related to your medical care, the University of Miami electronic system will show that you are a research participant and the consent form you sign will be included in your electronic medical record. In order to provide as complete a record as possible, some of your study-related research information may also be placed in your University of Miami medical record. This information will be

available to University of Miami health-care providers and other authorized University of Miami staff who may not be engaged in the research study but who are involved in the provision of your medical care. The confidentiality of the results and other documents in the University of Miami medical record will be governed by laws, such as HIPAA, that concern medical records.
It is suggested that you tell any non University of Miami provider that you are participating in University of Miami research and that this information may be made available at your request.

RIGHT TO WITHDRAW:

Your participation is voluntary. You have the right to withdraw or refuse to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The principal investigator can remove you from the study without your consent either because of your failure to follow the study, if he/she feels it is in your best interest medically, or for administrative reasons.

WHOM TO CONTACT

If at any time you have any questions about the study or in case of study-related injury, you may contact Vittorio Porciatti, at Telephone Number: Day 305-326-6050; Night: 786-543-1766

OTHER PERTINENT INFORMATION:

The principal investigator will answer any questions you may have regarding the investigation. If you have any questions about your rights as a research subject you should contact the Human Subjects Research Office at (305) 243-3195, Fax (305) 243-3328

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

I have read this informed consent form, in English, a language that I read and understand, and agree to participate in this study.

Printed Name of Subject

Signature of Subject

Date

_____ _____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent

Principal Investigator's Name: Vittorio Porciatti, Dsc
Telephone Number: Day_305-326-6050; Night Cell: 786-543-1766