Informed Consent statement for a (randomized/prospective) study comparing the efficacy of Selective Laser Trabeculoplasty versus Brimonidine tartrate 0.2%/ Timolol maleate 0.5% (Combigan, Allergan inc.) in lowering intraocular pressure as adjunct therapy in Primary Open Angle Glaucoma.

You are invited to participate in a research study focusing on the efficacy of Selective Laser Trabeculoplasty and Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) as adjunct treatment in primary open angle glaucoma. You were selected as a possible subject because, during your examination, your doctor determined that your glaucoma is not well controlled with your current medication. We ask that you please read this form and ask us any questions you may have before agreeing to be in the study.

The study, Protocol number [Insert protocol number], is being conducted by Ian McWherter, O.D. and colleagues at Bennett and Bloom Eye Centers 1935 Bluegrass Ave, Suite 200 Louisville, KY with approval by the Institutional Review Board at the University of Pikeville, Kentucky College of Optometry. There is no outside funding for this study. The 24 hour emergency phone number for Bennett and Bloom is 502-895-0040.

University of Pikeville, Kentucky College of Optometry has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

STUDY PURPOSE

The purpose of this study is to compare Selective Laser Trabeculoplasty (SLT) to the beta blocker and alpha-2 adrenergic agonist combination medicine Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) in lowering intraocular pressure as adjunct therapy in patients with Primary Open Angle Glaucoma who are not controlled on a prostaglandin analog alone.

All of the medications used in this study are approved by the Food and Drug Administration (FDA).

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 30 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

A baseline exam will be conducted that involves obtaining your ocular, family, and social history. Additionally, we will check your blood pressure, pulse, visual acuity, pupils, extra ocular muscles, intraocular pressure, and external ocular health. We will also evaluate how fluid drains from your eye using a procedure called gonioscopy. Lastly, we will measure the thickness of your corneas. The baseline exam may last 1-2 hours and several measurements of your intraocular pressure will be obtained to establish a baseline pressure for you. After your baseline exam you will be randomized to receive either topical medication, Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) twice a day, or Selective Laser Trabeculoplasty, which will be performed in the office or at the designated ambulatory surgery center. You will continue to take your current glaucoma medication during this study.

If you are assigned to the Selective Laser Trabeculoplasty group, the procedure will only take approximately five minutes to perform. During the laser procedure, you will see some flashes of light and hears some clicks. One hour after your procedure, we will check the pressure inside your eye and ask you to start taking one drop of Prednisolone Acetate 1% four times a day for the next four days to help reduce inflammation inside your eye and increase your comfort following the procedure.

If you are assigned to the Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) group, you will start using the drop twice a day in the study eye. Your doctor will not know which group you have been assigned to and will be masked to which drops you are or are not taking.

In either group you will also be asked to complete a drop diary documenting each date/ time you administer a drop, which eye it went in, how many drops went into your eye and any issues you experienced during the administration.

Eight weeks after starting the topical medication or having the Selective Laser Trabeculoplasty procedure performed, you will have a follow up examination to check your intraocular pressure and determine the efficacy of the treatment. At this exam, we will check your blood pressure, pulse, visual acuity, pupils, extra ocular muscles, intraocular pressure, and external ocular health.

Your participation in the study is estimated to last no longer than 10 weeks.

RISKS OF TAKING PART IN THE STUDY:

While participating in the study, the risks include:

The risks for Selective Laser Trabeculoplasty are minor and transient in nature, however you may experience mild pain, discomfort, red eye, blurred vision, or light sensitivity. Rarely, Selective Laser Trabeculoplasty may cause increased inflammation inside the eye or a spike in intraocular pressure, which may require further treatment.

The risks associated with topical Prednisolone Acetate 1% include an increase in intraocular pressure and cataract formation.

The risks associated with topical Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) include allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia (redness), eye pruritus (itching), ocular burning, and stinging.

You may have a hypersensitivity reaction (allergy) to any of these topical medications.

To help minimize these potential side effects of the Selective Laser Trabeculoplasty and topical medication, we will monitor you closely and follow up with you one hour after the procedure. Additionally, a doctor will be on call 24 hours a day to deal with any possible complications that arise throughout the study.

BENEFITS OF TAKING PART IN THE STUDY:

The benefits to participation in this study that are reasonable to expect is further knowledge about the effectiveness of Selective Laser Trabeculoplasty and Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.) as adjunct therapy to prostaglandin analogs in primary open angle glaucoma.

You, as a participant in this study, may benefit as both treatment groups have been shown to lower intraocular pressure. However, there is no guarantee that there will be a direct benefit to you. Results from this study may benefit others in the future.

ALTERNATIVES TO TAKING PART IN THE STUDY:

You do not have to be in this study to receive treatment for your glaucoma. Instead of being in the study, you have these options: You may have the Selective Laser Trabeculoplasty performed without participating in this study, you may add a topical medication to your treatment, you may choose no additional treatments, or depending on the level of severity you may need a more invasive glaucoma surgery to prevent vision loss. The study doctor will discuss with you the risks and benefits of the alternative treatments.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research

associates, University of Pikeville, Kentucky College of Optometry, the study sponsor, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) [for FDA-regulated research and research involving positron-emission scanning], the National Cancer Institute (NCI) [for research funded or supported by NCI], the National Institutes of Health (NIH) [for research funded or supported by NIH], etc., who may need to access your medical and/or research records.

PAYMENT

You will be paid $125.00 dollars for your participation in this study. This will offset any transportation costs and help compensate you for your time. Payment will be made in the form of a Visa Gift card, upon completion of the study, and will be mailed to you.

COSTS

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: All standard of care procedures, exams, and testing including the Selective Laser Trabeculplasty, the baseline exam, gonioscopy, pachemetry, and the eight week follow up exam. You will not be responsible for these study-specific costs: Prednisolone Acetate 1% or Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan inc.).

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

FINANCIAL INTEREST DISCLOSURE

There are no financial interest disclosures for this study.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, during normal business hours, please contact the research coordinator Janet Nutting at 502-214-3397. After business hours, please call 502-895-0040 to speak with the on call physician at Bennett and Bloom Eye Centers.

In the event of a life-threatening emergency, you should dial 911. For eye related emergencies, you may contact Bennett and Bloom Eye Centers at 502-895-0040.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to University of Pikeville IRB 147 Sycamore Street Pikeville, KY 41501 Attn: Cathy Thornsbury (Armington 219). You may also contact the IRB by phone 606-218-5219, fax 606-218-5212, or email at cathythornsbury@upike.edu.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose to decline participation or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Bennett and Bloom Eye Centers.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____

Date:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____

Date:_____