PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Prospective Study on DEXTENZA® Safety and Efficacy following concomitant MIGS and Cataract Surgery

STUDY DOCTOR: «First_Name» «Middle_Name» «Last_Name», «Suffix»

STUDY SITE: «Company_Name»
«Address»
«City_State_ZIP»

TELEPHONE: «Telephone»
«Telephone_2_if_applicable»

SPONSOR: Ocular Therapeutix

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. You will receive a separate consent form that sets forth the purpose, procedures, benefits, and risks of the cataract and glaucoma surgeries.

Dr. Radcliffe or the 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 Dr. Radcliffe or the 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 AND PURPOSE

You are being asked to participate in this study because you have been diagnosed with glaucoma and a cataract in at least one eye. After simultaneous surgery for glaucoma and a cataract, patients must take multiple eye drops daily to control glaucoma, prevent infection, reduce inflammation, and relieve pain. Taking many eye drops is a burden that can be confusing. Patients may forget to take some drops. This can cause issues like slower healing time and cystoid macular edema, which can block vision.

The purpose of this study is to compare the safety and efficacy of DEXTENZA® to steroid eye drops after glaucoma and cataract surgery. DEXTENZA® is a 3mm long gel-like cylinder that is inserted in the punctum, a natural opening in the lower eyelid. DEXTENZA® is activated by the

eye's moisture. DEXTENZA® delivers dexamethasone, a liquid corticosteroid, onto the surface of the eye automatically for up to 30 days after eye surgery. Dexamethasone is used to reduce inflammation and eye pain.

DEXTENZA® can be used to replace anti-inflammatory steroid eye drops, which may make recovery after eye surgery easier and safer for patients. In this study, we are comparing DEXTENZA® to the current standard of care, steroid eye drops (prednisolone acetate 1%), to see how safe and effective DEXTENZA® can be for eyes with glaucoma and a cataract. This is a randomized study, meaning that the eye you enroll for this study has an equal chance of receiving either the steroid eye drops or DEXTENZA®. If you choose to enroll both eyes, then one of your eyes will receive the steroid eye drops, while the other will receive DEXTENZA®. This is an open-label study, meaning that you will know whether your eye receives the DEXTENZA® insertion. DEXTENZA® is approved by the U.S. Food and Drug Administration (FDA) to treat inflammation and pain following eye surgery. It has not been tested in patients who are having glaucoma and cataract surgery at the same time, therefore its use in this study is investigational.

Approximately 40 or less men and women age 21 and older will be enrolled in this study, and all participants will be recruited from the New York Eye Surgery Center in the Bronx, NY. A total of 40 eyes will be involved in the study.

DURATION

You will be expected to participate in this study for 3 months after your surgery if you enroll one eye. If you enroll both eyes, you will be expected to participate for up to 6 months after your first eye's surgery.

PROCEDURES

If your medical record indicates that you meet the inclusion criteria for this study, Dr. Radcliffe will discuss the study with you during your regular clinic visit. If you agree to participate, your eye will be assigned by chance, like the flip of a coin, to either the DEXTENZA® group or the prednisolone acetate 1% steroid eye drops group before surgery. If you agree to enroll both eyes in the study, then the other eye will be assigned to the group opposite the first eye.

For the eye or eyes you enroll, you will receive minimally invasive glaucoma surgery and cataract surgery to treat your glaucoma and cataract. If your eye is randomized to receive DEXTENZA®, you will also receive an insertion of DEXTENZA® at the end of the operation. The operation without DEXTENZA®, including just glaucoma surgery and cataract surgery, typically takes 10-20 minutes. DEXTENZA® adds less than five minutes to the operation.

After the surgery, you will be expected to take antibiotic eye drops and glaucoma eye drops daily as standard of care for both eyes, unless Dr. Radcliffe states otherwise. If an eye received the DEXTENZA® insertion, you will not take steroid eye drops in that eye. If an eye does not receive the DEXTENZA® insertion, you will be required to take prednisolone acetate 1% steroid eye drops in that eye according to Dr. Radcliffe's instructions.

You will be asked to come to 4 post-surgery follow-up visits for each eye you enroll, lasting approximately 15-30 minutes each, as follows:

- 1 day after surgery
- 1 week after surgery
- 1 month after surgery
- 3 months after surgery

If you enroll both eyes, you will attend eight follow-up visits in total.

All follow-up visits would be scheduled to check on your recovery even if you did not participate in this study. Standard of care assessments such as visual acuity, visual field testing, ophthalmic examination, recording side effects, and intraocular pressure measurements will be performed at some or all follow-up visits.

At the 1 month follow-up and the 3 month follow-up visits, you will also be asked to complete a 12-item questionnaire called the Ocular Comfort Index. This questionnaire will ask about how one eye feels. It will take about 5 more minutes to complete the survey. If you have difficulty reading, staff members will read to you the questionnaire in your preferred language for you to answer verbally.

During this study, you are responsible for following Dr. Radcliffe's instructions on treatment plan, coming to appointments on time, and reporting any issues you notice to Dr. Radcliffe or staff.

POTENTIAL RISKS, SIDE EFFECTS, DISCOMFORTS, INCONVENIENCES

Use of corticosteroids on the eye, whether they are steroid drops or sustained-release inserts like DEXTENZA®, can worsen glaucoma with damage to the optic nerve by increasing intraocular pressure. Corticosteroids may suppress the immune system and increase risk for bacterial infection, fungal infection, and viral infection. The use of steroids after eye surgery may delay healing and increase the incidence of bleb formation.

DEXTENZA® may be ineffective. DEXTENZA® may cause discomfort in the eye. DEXTENZA® may involve risks that are unforeseeable to you, an embryo or fetus you carry, or an infant you are nursing. DEXTENZA® may involve additional risks that are currently unknown.

POTENTIAL BENEFITS

If your eye receives DEXTENZA®, a potential benefit is that you will not have to take steroid eye drops in that eye after surgery. DEXTENZA® may potentially be more comfortable and/or convenient than steroid eye drops. There is no guarantee that DEXTENZA® will help you.

The results of this study will benefit future patients by providing clinical evidence comparing the safety and efficacy of DEXTENZA® to steroid eye drops in eyes with glaucoma and a cataract.

ALTERNATIVE TREATMENTS

You can choose to receive DEXTENZA® without participating in this study. You can opt for the standard of care steroid eye drops without participating in this study. Alternatively, you can choose to receive a different type of sustained-release dexamethasone. The FDA-approved injection known as DEXYCU® is one example. DEXYCU® is injected inside the eye, behind the iris of the eye. No currently published study has compared DEXTENZA® to DEXYCU®, so the relative advantages and disadvantages are not clearly known.

NEW INFORMATION

You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

COMPENSATION TO YOU

You will receive $10.00 for each completed follow-up visit. A completed visit means all scheduled study procedures have been carried out. If you have one eligible eye and enroll that eye, you can receive a maximum of $40 total from 4 follow-up visits. If you have two eligible eyes and enroll both, you can receive a maximum of $80 total from 8 follow-up visits.

COSTS TO YOU

Insertion of DEXTENZA® and completion of study-related questionnaires are being done only for this study. Therefore, you and your insurance provider will not be billed for these procedures. You will not be charged for any pre-operative or post-operative clinic visits related to the study and will not be charged for study procedures that occur during those clinic visits. You and/or your insurance provider **will be** responsible for the costs of the glaucoma and cataract surgery and all medications related to your surgery.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to participate is entirely voluntary. You may elect to receive alternative treatment. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision to be in this study or to withdraw from the study. If you decide to withdraw from the study, please talk to Dr. Radcliffe to make sure this is done safely.

Your participation may be stopped without your consent by Dr. Radcliffe or the FDA for any reason. For example, your participation may be stopped:

- if you do not undergo your second eye's surgery within 90 days of the first surgery
- if it is deemed to be in the best interest of your health and welfare.
- if you fail to respond to the study implant.
- if your disease worsens or you have severe or unacceptable side effects.
- if you fail to follow instructions.

STUDY COMPLICATIONS AND COMPENSATION

Every effort to prevent a study-related injury will be taken by Dr. Radcliffe and staff. Medical care will be made available to you to treat any physical injury incurred by you as a direct result of the study procedures. In the event you are injured as a direct result of the study in accordance with Dr. Radcliffe's instructions and the study protocol, you should immediately contact Dr. Radcliffe and emergency treatment will be provided. Medical care for research-related injury will be provided by Dr. Radcliffe or another physician at the New York Eye Surgery Center at zero cost to you.

You agree to cooperate in obtaining any proceeds from insurance or other third-party coverage that may be available. No financial payments or other forms of compensation (such as lost wages, physical therapy or other recovery needs, other loss of income or pain or suffering or discomfort) have been set aside for such injuries; however, you do not waive any of your legal rights or release anyone from liability for negligence by signing this document.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

Under the privacy laws, you have the rights to decide who can use your protected health information (called PHI). When you sign this form, you are saying that you will allow the use of your protected health information for this study.

The information that will be collected about you as a part of this research includes:

- Name
- Address
- Telephone number
- Birth date
- Race
- Sex
- Family medical history
- Allergies
- Medications you take (current and past)
- Information from the physical examination done by Dr. Radcliffe
- Results of study tests and study procedures
- Other information from other doctors' offices, clinics, and/or hospitals that is needed for the study

Information collected about you for the study will be kept in a research file that is separate from your medical chart. You will not be able to see your research file until after the end of the study.

The study team will know your identity; however, your records will be labeled with a code that is randomly assigned to you. The research staff are the only people who will have this code and its key.

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- The study sponsor (or sponsor representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Sterling Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)
- Other government agencies in other countries
- Other doctors, health care professionals or research staff who are involved in the study

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

This permission (also called an authorization) will have no end date.

You have a right to see your study records; however, you will not be able to see your study records until after the study has ended.

You may also take away (or withdraw) your permission for the use of your protected health information at any time. If you choose to withdraw your permission, you must write your Dr. Radcliffe a letter.

Dr. Radcliffe's mailing address is the New York Eye Surgery Center, 1101 Pelham Pkwy N, The Bronx, NY 10469. Dr. Radcliffe will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

A description of this research study 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.

QUESTIONS

If you have questions, concerns or complaints about the research study or you experience a research-related injury, please contact Dr. Radcliffe at (201) 925-0476 or the study staff at (718) 519-1000.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

PARTICIPANT STATEMENT AND AUTHORIZATION

I have read or have had read to me the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I agree to participate voluntarily in this study. I give my permission to Dr. Radcliffe to use and disclose my protected health information as described in this consent form.

I will receive a signed copy of this form, which has 8 pages.

All my questions have been answered.

I have not waived any of my legal rights by signing this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date
(if other than the Principal Investigator)

_____ _____
Signature of Principal Investigator Date