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INTEGREVIEW IRB
NOVEMBER 12, 2019

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

NAME OF SPONSOR COMPANY:	Daniel F. Goodman, MD
PROTOCOL NUMBER AND TITLE OF STUDY:	PXL-2211; "Safety and Effectiveness of the PXL-Platinum 330 System for Corneal Cross-Linking in Eyes with Corneal Ectasia"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/ INVESTIGATOR):	Daniel F. Goodman, MD
TELEPHONE NUMBER(S), DAYTIME& AFTER HOURS:	415-474-3333

You ("you" refers to you or your child throughout this consent form) are deciding if you would like to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Goodman Eye Center is conducting a research study. You were selected as a possible participant in this study because you have corneal ectasia in one or both of your eyes. Your participation in this research study is voluntary.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

The investigator is the sponsor and is paying for this study.

Why is this study being done?

The purpose of this study is to evaluate the safety and effectiveness of the PXL Platinum 330 UV light system when used to treat conditions where the cornea of the eye is thinning.

This study treatment will expose your cornea to ultraviolet (UVA) light in conjunction with the drug riboflavin. This process is designed to strengthen the corneal structure, slow or stop corneal thinning and improve the corneal shape.

There are some things to know before deciding to be in this study and have the study treatment:

- This study treatment has not been approved by the FDA. The study device is not approved by the FDA. A similar device is the standard treatment for keratoconus and corneal ectasia in Europe and other parts of the world and was recently approved in the US in April 2016. However, the approved device requires that the cornea be scraped as a part of the procedure. In this study, we will be evaluating the use of a new device that is able to strengthen the cornea and does not require scraping of the cornea surface.
- Having this study treatment is entirely voluntary. No one can make you participate.
- If you decide to have this study treatment you can change your mind later and leave the study.
- The costs for this study treatment will not be covered by your insurance.

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- The amount you will be charged ($4,000 for each eye, plus the cost of medications) will cover the pre- and post-op evaluation for the duration of the study.
- You will not be allowed to be enrolled in any other clinical trials while you are participating in this study.

In this document, you may see the terms "medication", "treatment", and "treatment period"; these are terms used in research studies as mentioned above, this does not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

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

About 500 subjects, ages 10 and up are expected to be in the study. If you volunteer to participate in this study, the researcher will ask you to do the following:

Overview of Study Treatment Procedures

- A device (speculum) will hold your eyelids open during the procedure.
- An eye drop containing riboflavin (vitamin B2) will be placed onto your eye.
- The riboflavin drops (less than 1/5 of a teaspoon total) will be placed in the eye at one minute intervals for 15-30 minutes. Then we will measure the thickness of the cornea.
- After the cornea is saturated with riboflavin, you will lie down with the treatment eye under the UVA light.
- Your UV treatment will be randomized between two different energy levels, as we are trying to determine if there is a difference in safety and efficacy between these two treatment arms.
- The estimated time in the clinical facility is approximately 2.5 to 3 hours.
- The effect of this study treatment will be evaluated over the 12 months following the treatment.

Screening Procedures

- Before study treatment, we will examine your eyes to confirm that you have a condition that causes corneal ectasia (keratoconus or ectasia or non-responding corneal ulcer from infection) and collect a health history to determine that you don't have any conditions that would prevent you from being in the study.
- You must also indicate that you are aware of the worsening of your vision and your medical history must confirm a decrease in vision over time.

Study Treatment Procedure

- Once in the room where the study treatment will take place, you will be positioned to make you comfortable, and then numbing eye drops will be put into the eye to be treated.
- Drops (riboflavin) will be placed in your eye for fifteen to thirty-minute period. Your eye will then be checked to assure that your cornea is soaked with riboflavin. A speculum will be used to keep the eye open during the procedure. It is possible that more drops will be applied. The study treatment with the light will last approximately 20-45 minutes. During the study treatment, the UVA light is turned on and you will need to look at it. Do not worry if there is some movement of your eye. After the study treatment, a bandage soft contact lens may be placed on your eye. You will be able to see through this special lens, although your vision may be blurry. This stays on your eye for about one to five days

until the surface of the eye heals. You will also be given drops to use in your eyes during the healing process.

- You can go home after the study treatment, but someone will need to drive you because your vision in the treated eye will be more blurred than it was before the procedure.
- You can expect your treated eye to be scratchy and/or uncomfortable for a few days after study treatment. The bandage contact lens and some of the drops you will be taking home with you will help make your eye feel better, but they will not make it feel completely normal.
- You will be given a prescription for pain medication that you can take if you need it.
    - If you take the pain medication, it may make you drowsy and you should not drive, operate heavy or dangerous equipment, or drink alcoholic beverages. Please refer to the instruction sheet that your pharmacist gives you for other warnings and possible side effects of the pain medication.

Post-Operative Care

Prescriptions for postoperative medications and written postoperative instructions will be given to each subject and reviewed before discharge. The following postoperative eye drops will be prescribed (you may need to pay for the cost of these medications):

- Antibiotic eye drops to prevent infection
    - For 4 to 7 days
- Steroid ophthalmic suspension
    - For 4 to 7 days
- Preservative-free artificial tears
    - Every hour while awake for at least 48 hours

Follow-Up Visits (Days 1-2, Months 3, 6, and 12 after the procedure)

Examination testing to be completed at follow-up visits may include all or some of the following depending on post-operative time frame:

- Visual acuity (how well you can see)
- Refraction (how your eyes correct with lenses)
- Intraocular pressure (the pressure inside your eye)
- Corneal thickness and shape assessment
- Endothelial cell count
- Wavefront aberrometry scan
- Eye examination with the slit-lamp

We will numb your eyes with numbing drops before doing these tests.

How long will I be in the research study?

Participation will take a total of about 12 months.

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Are there any potential risks or discomforts that I can expect from this study?

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

This study involves the following risks:

- Very likely: Mild pain for first few days and visual fluctuation (changes in vision) for first few weeks.
- Less likely but serious: continued progression of corneal ectasia.
- Rare: Scarring or loss of vision; corneal infection.
- The treatment may not work, and your corneal ectasia might progress despite the study treatment, in which case you might receive other procedures (e.g., Intacs, corneal transplant)
- Visual fluctuations needing change in glasses or contacts

Other risks of this study include:

- Clouding or hazing of the cornea,
- Endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling);
- Ptosis (droopy eyelid);
- Corneal swelling; contact lens intolerance;
- Increased dry eye; rosacea; corneal epithelial defect.

There may also be other risks that we cannot predict.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Are there any potential benefits if I participate?

Your keratoconus or corneal ectasia or corneal infection may stabilize or improve after this study treatment, but it might stay the same or it might get worse. We hope that others with your condition may benefit from the information gained from this study.

The results of the research may demonstrate the safety and effectiveness of a new device (the PXL-330) for corneal crosslinking, and its ability to induce the crosslinking effect more rapidly with no removal of corneal surface cells.

What other choices do I have if I choose not to participate?

You will receive conventional treatment for corneal conditions (e.g., antibiotics for infections) whether or not you participate in this study. For keratoconus or non-infectious causes of ectasia, you will be offered treatment with the FDA-approved collagen crosslinking device.

Will I be paid for participating?

You will not be paid for participating in this study.

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Will there be Additional Costs?

The cost for the pre- and post-op evaluation and management is $4,000.00 per eye, plus costs for routine medications (e.g., eye drop steroid and antibiotic) after the procedure. You will be responsible for paying these fees.

What if I am injured while participating in the study?

You do not waive any liability rights for personal injury by signing this form.

All forms of medical diagnosis and treatment, whether routine or experimental, involve some risk of injury. In spite of precautions, you might develop medical complications from participating in this study. If such complications arise, the study doctor will treat you as needed, at no charge, for any physical injury caused directly by this study. The study doctor will not offer to cover the medical care costs for injuries or illnesses that are not caused directly by the study. No other form of compensation will be offered.

Will information about me and my participation be kept confidential?

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained in the following manner:

Your records of participating in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The study doctor and study staff
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB
- The United States Food and Drug Administration (FDA)

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location. The results of these study treatments may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

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

- You will not lose any of your legal rights by signing this consent form.
- You can choose whether you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and remain in the study.

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The investigator, the sponsor company, FDA, or IntegReview, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- Failure to do required follow up visits

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

Who can I contact if I have questions about this study?

If you have any questions, comments or concerns about the research, or to report a research related injury, you can talk to the one of the researchers. Please contact:

Daniel F. Goodman, MD
Daytime and after hours number 415-474-3333

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

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IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation, we will tell you. You can then decide if you still want to be in the study.

You will be given a copy of this signed and dated consent form to keep for your records.

SIGNATURE OF STUDY PARTICIPANT

_____
Printed Name of Minor Study Subject

_____
Printed Name of Parent, Guardian or Legally Authorized Representative

_____ _____
Signature of Parent, Guardian or Legally Authorized Representative Date

_____
Printed Name of Adult Study Subject

_____ _____
Signature of Adult Study Subject Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Principal Investigator Date

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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ASSENT FORM FOR MINOR STUDY SUBJECTS

10-17 years of age

You are being asked to be in a research study about the use of ultraviolet light with vitamin eye drops to help the cornea (front window) of your eye to be strengthened because you have thinning or weakening in that part of your eye. A research study is a way to learn more about the PXL 330 system (a small device that delivers ultraviolet light to your eye) and its uses.

If you decide that you want to be a part of this study, you will be asked to undergo a procedure in the office. The procedure will take about 45 minutes. First, one or both of your eyes will be numbed with numbing eye drops. Then you will receive Vitamin B2 drops in your eye for about 15 to 30 minutes. You will lie down underneath the ultraviolet light for 20 to 45 minutes in one or both of your eyes; there will be an eyelid opener to help keep your eyes open. After the procedure, there may be pain for a few days. You will be given medicine for pain if you need it. The total time you will be in the office is about 2.5 to 3 hours. After the procedure, you will be asked to come back to the office six times over the next year.

There are some things about this study that you should know. They are: you may feel some pain for a few days, your vision may change for a few weeks, or the procedure may not work.

When you come back for each study visit we will:

- Do a vision exam using the eye charts to help us know how well you are seeing
- Check the pressure in your eyes
- Measure the thickness of the cornea (front window) of your eye
- Use a microscope to look more closely at your eye
- We will give you numbing eye drops for any of these tests so you will not feel pain.

This study will last about one year and will include up to 6 visits to the investigator's office.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be to improve the thinning or weakening of the cornea (the front window in your eye).

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. You can say no and no one will be mad at you. If you decide to stop after we begin, that's okay too.

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Statement of Assent: I have read or someone has read to me this assent form. My parent(s) or my legally authorized representative (if applicable) and the investigator have explained the study to me and have answered my questions. I agree to be in this study.

_____
Printed Name of Minor Study Subject

_____
Signature of Minor Study Subject Date

_____
Printed Name of Person Explaining Assent Form

_____
Signature of Person Explaining Assent Form Date

You (and/or your legally acceptable representative) will be given a signed and dated copy of this consent form to keep.