

Information and Assent Form  
Ages 12-17  
CXLUSA  
CXL-1

## INFORMATION AND ASSENT FORM

Ages 12-17

**Study Title:** Collagen Crosslinking with Ultraviolet-A in Asymmetric Corneas  
**Study #:** CXL-1  
**Sponsor:** CXLUSA  
**Study Doctor:** Daniel F. Goodman MD

Daniel F. Goodman, MD, A Medical Group, Inc.  
2211 Bush St., 2nd Fl.  
San Francisco, CA 94115

**Telephone Number:** (415) 474-3333

**After Office Hours:** (415) 474-3333

### This form explains:

- Why this study is being done.
- What will happen during this study and what you will need to do.
- If anything bad can happen to you in this study.

Ask the doctor or nurse if you have any questions before you make up your mind about being in the study. You can also talk to your mom or dad and ask to read the information the doctor gives them.

### Do I have to be in this study?

**You do not have to be in this study if you don't want to.**

If you choose to be in the study, then you can sign this form. If you **do not** want to take part in this study, you should **not** sign the form.

Even if you say you want to be in the study now, you can stop later if you change your mind. If you change your mind later, tell the doctor.

### Why is this study being done?

Dr. Goodman wants to find out if a procedure that shines ultraviolet light and adds eye drops of vitamin B (also called riboflavin) to children's eyes can help children's vision. This is called a "research study."

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You might have the study procedure done on both eyes or on only one eye. If it is done on both eyes, you might have to go the doctor's office on two different days to have this done.

### **What will happen to me in this study?**

If you want to be in the study, you will have the study procedure done once to your eye or eyes and you will come into the office for about six study visits. The doctor or nurse can talk to you about what will happen at each visit.

Here are some things the doctor or nurse will do at your visits to the doctor's office.

- Test your eyesight both with your glasses or contact lenses on and without them.
- Look at your eyes using special instruments.
- Ask you about your medical history and the your past eye care.
- Ask if you have taken any medicines.
- Ask you to fill out a questionnaire.
- Perform the study procedure on your eye or eyes. If you have questions about the study procedure, ask the doctor or your parents about what will happen during this procedure. When the procedure is done, the doctor will put a contact lens bandage over your eye or eyes. The doctor or nurse will give you eye drops to put in your eyes at home. You will probably have to use the eye drops for several days, and you might have to use eye drops for several weeks. The doctor will tell you when and how long to use them.
- You will come in to the doctor's office for about 4 follow-up visits over 8 months after the study procedure day. During the follow-up visits the doctor will check the health of your eyes, perform some tests, and test your vision again, but the doctor will not do anymore eye surgery procedures. The doctor will also ask you to answer some questions about how you are feeling and if the study procedure is helping your eyes.

If you do not want to do any of these things, you can say you do not want to be in the study.

### **Will being in this study help me?**

The study procedure may help your eyesight, but there is no guarantee that being in this study will help you. Your eyesight might not get better or may even get worse while you are in this study. This study might help doctors come up with new tests or medicines to help other people in the future.

### **Can anything bad happen if I am in this study?**

Although this procedure has been used for more than 10 years, there may still be some risks or side-effects that are not known yet.

You might feel pain in your eye or blurred vision that can last up to 5 days from having the top layer of tissue removed from your eye. There is also risk of infection, redness in your eye, hazy vision, dry eyes, and slow healing of your eye.

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The most common things people have from using riboflavin drops in their eyes are blurry vision, and mild redness or stinging in their eyes. Allergic side effects can also happen. When this happens people usually have one or more of the things on this list:

- a rash (red or rough skin)
- a hard time breathing,
- wheezing
- a sudden drop in blood pressure
- a fast pulse
- sweating or swelling around the mouth, throat, or eyes.
- itching of the eye
- eye redness
- eyelid swelling/redness

The most common side effects of shining the ultraviolet light in your eyes are blurred vision and red or stinging eyes. Another side effect of this is if too much UV light shines in the eye it can damage the eye. This can cause loss of sight for 24 to 48 hours. It may also require more eye surgery. Another side effect may be unwanted changes to your eye.

The most common side effects of antibiotic eye drops, used to prevent infection, include: pain, swelling, burning, dryness, or itchiness of the eye.

It is rare, but a serious infection or inflammation can make you lose your sight permanently, or even lose an eye. More surgery may be needed if this happens.

You should tell your mom or dad right away and get medical help if you feel any of these things.

You might also feel other things. While you are in the study, you have to tell the doctor or your mom or dad if you feel sick or if you take any medicines. You or your mom or dad can call the doctor at the number on the first page of this form.

Could I have problems if I can't use my regular contact lenses?

If you want to be in this study, you might not be able to use your regular contact lenses on some days during the study. The doctor or nurse will talk to you about this if you have to stop using contact lenses. If you stop wearing your regular contact lenses to be in the study, your vision might be unclear at times and this could make you uncomfortable. Please tell the doctor or nurse right away if you have any problems when you stop wearing your regular contact lenses.

**Are there risks to me if I am pregnant during the study?**

Girls cannot be in this study if they are:

- pregnant
- planning to become pregnant during the study
- nursing a child

If a girl is pregnant or nursing a child while having the study procedure, there may be risks to the unborn baby or nursing child. Nobody knows what these risks are right now.

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If you think you are pregnant during the study, you must tell the doctor immediately. If you become pregnant, you may have to leave the study. The doctor may ask for information about the pregnancy and the birth of the baby. The doctor may share this information with the sponsor and Quorum Review.

**Who can you talk to about the study?**

You can ask questions about the study any time. You can call the doctor any time.

If you want to ask questions about what it means to be in a research study, you or your mom or dad can call Quorum Review at 1-888-776-9115 (toll free).

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**Do you want to be in this study?**

Please sign below if you want to be in this study, but remember: You don't have to be in this study if you don't want to.

\_\_\_\_\_  
Name of Child (Print)

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Signature of Child

\_\_\_\_\_  
Date

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

\_\_\_\_\_  
Name of Person Explaining Assent (Print)

\_\_\_\_\_  
Signature of Person Explaining Assent

\_\_\_\_\_  
Date

I attest that I or my representative discussed this study with the above-named participant.

\_\_\_\_\_  
Signature of Principal Investigator or Sub-Investigator

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