

## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

### **Project Title:**

### **Visual and Optical Performance of Spherical, Aspheric and Toric Soft Contact Lenses**

### **Principal Investigator(s):**

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### **Purpose of the Study:**

Contact lenses improve vision by correcting optical errors such as near sightedness or astigmatism. Astigmatism is one kind of optical error that causes blurred vision, and can be corrected with a specially designed contact lens. The purpose of this study is to test three kinds of soft contact lenses to see how well they correct astigmatism. These lenses have been used successfully in the United States but are new to Japan. We are interested in seeing how well they work on Japanese or East Asian eyes.

### **Procedures and Duration:**

If you volunteer for this study we will ask you to attend two sessions: 1) a pre-fitting screening exam and 2) a lens evaluation exam.

#### 1. Pre-fitting screening exam (about 45 minutes).

The purpose of the pre-fitting screening exam is to measure your eyeglass prescription, collect basic measurements of your eyes and make sure that your eyes are healthy enough to wear soft contact lenses. Based on the results we will decide if you can proceed to the lens evaluation exam. Some of the tasks you will be asked to perform are to

- Complete a registration form with your name, phone number, and social security/student ID number
- Gaze into two machines that will measure your eyeglass prescriptions
- Sit for a standard eye exam to measure your eyeglass prescription and let a doctor check the health of your eyes. We will not dilate your pupils or use eye drops.

(Note that, since we will not dilate your eyes, this will not be a complete eye exam. If you wish to have a complete eye exam, including dilation and a check of the health of the back of the eye, you should schedule a separate exam with an eye doctor. We recommend that you do this if you have not had a complete eye exam within the past two years.)

## 2. Lens evaluation exam (about 3 hours on another day)

The purpose of the lens evaluation exam is to try three kinds of soft contact lenses on your eyes and see how well they correct vision. First we will put a pair of soft contact lenses on your eyes, and then you will

- wear the lenses for about 20 minutes and answer a questionnaire about how well you see.
- A doctor will examine your eyes to see how well the lenses fit.
- We will test your vision by asking you to read several different eye charts.
- You will gaze into two machines that will measure the optical quality of the lenses.

We will repeat these procedures with a second and third pair of soft contact lenses. Each of the lens pairs has a different design and your vision may be different with each pair.

### **Discomforts and Risks:**

There is no significant risk involved in any of the procedures. We will not use any experimental procedures, drugs or eye drops, and nothing will touch your eyes except for the contact lenses. The only risks are those involved with the wear of soft contact lenses for a short time. You may feel the lenses on your eyes for a few seconds after insertion, but soft lenses are not uncomfortable. Your eyes may tear for a few seconds after lens insertion and vision may be slightly blurry until the lens stabilizes. If you encounter any problems, please notify Dr. Salmon or another investigator. We will assist you and if necessary remove the lenses.

### **Benefits and Compensation:**

The information we gain from this study may help doctors in Japan do a better job of prescribing soft contact lenses for patients who have astigmatism. By participating in this study, you will be indirectly helping people improve their vision.

If you complete the pre-fitting screening exam, and we are able to measure your eyeglass prescription, we will give you a copy of the prescription at no charge. If you complete the lens evaluation exam we will pay you \$30.

If your eyeglass prescription does not fit the requirements of our study or we determine that, for health or other reasons, you should not be fit with contact lenses, we may dismiss you without providing any benefits. We will not dispense contact lenses to you at the end of this study. You will not have property rights or ownership interest in products or data that may be derived from your participation.

### **Statement of Confidentiality:**

We will record your name on the original data record so we can correctly link the various items of data together. After we complete the lens evaluation exam, the raw data will be transferred to Excel spreadsheets for analysis and Dr. Salmon will replace your name with a code to protect your confidentiality. Only study investigators will know how to link your name and the code. The original forms, which contain your name, will be

stored in a file cabinet in Dr. Salmon's office, which will be locked whenever he is gone. No one outside the study will be able to identify the connection between you and your data in any records or communications.

We will ask for your telephone number so we can contact you during the study. After the study, we will destroy all documents with your telephone number.

NSU requires that we collect your social security or student ID number in order to pay you. You may refuse to give your social security or student ID number, but then we may not be able to pay you. If you give us these numbers, all documents with those numbers will be destroyed at the end of the study.

All data collected during this project will be stored indefinitely to allow Dr. Salmon continuing access to the data, which may have scientific value for future research. In no case will your name or identity be disclosed to anyone else.

**Right to Ask Questions:**

Please feel free to ask questions at any time, or to contact Dr. Salmon to talk about the study. His contact information is at the top of this document.

For questions about your rights while participating in this study, you may contact the Institutional Review Board at Northeastern State University at 918-456-5511 or visit their web site at [www.nsuok.edu](http://www.nsuok.edu).

**Voluntary Participation and Right to Withdraw:**

Participation in this study is voluntary. You may withdraw at any time and may also decline to answer any questions that you do not wish to answer. You can end your participation at any time by telling Dr. Salmon or the other investigators.

**My signature below indicates that I have read the information above and that I agree to participate in this study. You will be given a copy of this consent form to keep with your records.**

\_\_\_\_\_  
**Signature of Participant**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Printed Name of Participant**

\_\_\_\_\_  
**Investigator's Signature**

\_\_\_\_\_  
**Date**