INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH STUDY

Non-Traditional IOP Measurements with PROSE

Sponsor:	BostonSight
Protocol Number:	BFS-KR-IOP-02
Principal Investigator:	Daniel Brocks, MD BostonSight 464 Hillside Avenue, Suite 205 Needham, MA 02494
24-Hour Emergency Telephone Number:	(617) 755-5929

You are invited to participate in a research study to evaluate various methods on measuring intraocular eye pressure with PROSE wear. You were selected as a possible subject because you are a PROSE wearer and wear a device of 18.0mm diameter or larger in both eyes. This study includes only individuals who voluntarily choose to participate. Please take your time to make your decision. Discuss it in confidence with your regular doctor, friends, and family if you want. Be sure to ask questions about anything you do not understand in this document.

The study is being conducted by Daniel Brocks, MD and Kellen Riccobono, OD, FAAO of BostonSight.

STUDY PURPOSE

The purpose of this study is to investigate the reliability of various methods of intraocular eye pressure measurements with a PROSE device of 18.0mm diameter or larger on the eye. The eye pressure in both eyes will be measured using one of the three instruments under investigation. The instrument used will be determined by order of enrollment in the study.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of up to 33 subjects who will be participating in this research.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If new information in relation to the study becomes available that may be relevant to the purpose and safety of the study and your willingness to continue participation in this study, you will be informed by the study doctor.

PROCEDURES FOR THE STUDY:

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

<u>At your visit (about 60 minutes)</u>

- The assessment completed during this vist are for research purposes only and are not part of your standard clinical care.
- We will collect information regarding your medical history and medications that you are taking at the time you enroll in the study.
- You will be asked to read a letter chart from distance to measure your vision.
- A slit-lamp examination, using an instrument that provides a magnified view of the front parts of the eye will be completed. This includes examining the health of the front of your eye and the proper fit of the PROSE device. During the examination, we will instill an orange fluorescent (sodium fluorescein) dye into your eyes. This dye is used in standard eye exams to visualize the tear film and check for irritation on the surface of the eye and does not cause discomfort. The procedures are similar to the ones done during your eye exam at a regular contact lens clinic.
- The IOP will be measured using the standard Tonopen after the your lens has been removed.

- The eye pressure of both eyes will be measured using one of three methods, with the PROSE device in place.

  - An anesthetic drop will be instilled into both eyes followed by a lubricating eye drop (Refresh Plus).
  - In this study, eye pressure will be measured via various methods that rely on contact with different parts of the eye.
  - This will be immediately followed by measurement of **both eyes** with **one** of the following instruments:
    1. Pneumatonometer: This consists of a small probe that will apply light pressure on the white of your eye (sclera) as you look down and inward.
    2. Diaton: A metal probe will apply light pressure on the upper eyelid to check the eye pressure as you look down.
    3. Tonopen: A small probe will lightly contact the white of your eye (sclera) as you look down and inward.
  - Measurements may be done multiple times to obtain an accurate measurement. After these measurements the conjunctiva will be evaluated.
  - All instruments used are, FDA approved and used currently in regular eye doctor's offices.

All study visits will be conducted at BostonSight.

<u>What is the time commitment for this study?</u>

- You will be enrolled in the study for approximately 1 day.
- Your visit will last approximately 60 minutes.

<u>RISKS OF TAKING PART IN THE STUDY</u>:

The risks involved with these measurements include an abrasion (‘cut’ on the eye) during measurement. Additionally, the anesthetic (‘numbing’) drop instilled before measurement can cause stinging or burning on instillation and rarely keratitis (corneal inflammation) which can be treated with artificial tears or anti-inflammatory eye drops.

The orange fluorescent dye (sodium fluorescein) used in this study usually causes no irritation, is used in standard eye examinations, and therefore should provide minimal irritation or risks. If your eye does become irritated, we will stop testing and instill artificial tears to soothe your eye.

The PROSE devices will be worn during the study. Adverse events and/or complications in daily wear of contact lenses are extremely rare. When contact lenses are worn on a daily wear basis there is a small risk of an adverse event compared to not wearing contact lenses.

There is also a potential risk of loss of confidentiality. This risk has been minimized by the investigator as outlined in the "Confidentiality" section.

There may be risks to being in this study that we cannot predict.

Side effects occurring during the trial can be treated by the study doctor, if this is deemed necessary. It is important that you inform the study doctor any unusual or unpleasant effects which you should feel.

BENEFITS OF TAKING PART IN THE STUDY:
If you agree to take part in this study, there may not be direct medical benefit to you. Information learned from this study may benefit others in the future. Information from this study may help the community to better understand the effects of eye pressure from PROSE and scleral lenses.

COMPENSATION FOR PARTICIPATION:
A $20 gift card will be given to each participant at the conclusion of the study.

ALTERNATIVES TO TAKING PART IN THE STUDY:
Instead of being in the study, you can decide not to participate. You may continue to participate in the PROSE program with BostonSight without participating in this study.

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, the submitted Institutional or Independent Review Board and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), who may need to access your medical and/or research records.

By signing this document, you give permission to access your medical records, including after withdrawal, for data verification purposes.

The results from the study, including laboratory tests, may be published for scientific purposes,

but your identity will be kept confidential.

In the rare event that your information is required to be disclosed by law to another entity, privacy laws may not apply.

COSTS

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study. There is no cost associated with participation in this study.

COMPENSATION FOR INJURY

If you get hurt or sick while you are in this study, and the study doctor reasonably determines your illness or injury to be a direct result of the study, medical treatment for costs that are not reimbursed or covered under your medical insurance to treat your illness or injury will be provided at no cost to you. If you have not followed the study doctor's instructions about the study, your expenses may not be paid.

Your health plan might not cover the costs of study-related injuries. To ask questions about this, talk to the study doctor or study staff.

YOUR RIGHTS AS A RESEARCH SUBJECT

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Not participating or leaving the study will not result in any penalty or loss of benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first.

YOUR RESPONSIBILITIES AS A RESEARCH SUBJECT

You will be asked to adhere to all instructions issued by the study doctor and other study staff. This includes either not wearing PROSE or wearing PROSE as well as arriving on time for examinations. Furthermore, you should answer all asked questions truthfully.

Should you not comply with instructions, the study doctor may stop your study participation. Your study doctor may also exclude you from this trial if he/she deems it beneficial for your health, or if you do not meet the study requirements. Your participation in this study may be ended at any time for any reason by the investigator.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions, concerns or complaints about the study or a research-related injury during office hours (i.e. 7:30AM-4:00PM), contact the Research Coordinator, Estelle Crowley at 781-726-7506. If you cannot reach the Research Coordinator during regular business hours (i.e. 7:30AM-4:00PM), please contact Dr. Kellen Riccobono at 781-726-7337.

After business hours, or in the event of an emergency, you may contact BostonSight's emergency line at 617-755-5929 for an on-call doctor.

This research is being overseen by New England Independent Review Board (IRB). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-(617) 243-3924 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Although New England IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean New England IRB has approved your being part of the study. You need to read the information in this informed consent form for yourself and decide whether or not you want to be in this study.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Not participating or 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 regular care at BostonSight.

The study doctor can withdraw you from the study at any time, even if you want to continue to be in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The study stops for any reason.

If you want to stop being in the study, you are encouraged to tell the study doctor or a member of the study staff. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. Please check box below:

☐ Yes, I agree to take part in this study.

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all of my questions to my satisfaction. I voluntarily agree to be in this study.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed and dated copy of this consent form for my records.

Subject's Printed Name: _____

Subject's Signature: _____ Date: _____

Printed Name of Person Explaining Consent: _____

Signature of Person Explaining Consent: _____ Date: _____