Official Title:	Optic Nerve Head Structural Response to IOP Elevation in Patients With Keratoconus
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NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	**Optic Nerve Head Structural Response to IOP Elevation in Patients with Keratoconus** Study Number: S17-01360
Principal Investigator:	Gadi Wollstein, MD Department of Ophthalmology *222 East 41st Street, Room 476* New York, NY 10017 929-455-5530
Emergency Contact:	Ann Ostrovsky, MD 646-385-4106

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to examine how the lamina cribrosa, a layer of tissue in the back of the eye, responds to increasing the pressure in the eye. This study involves subjects who were diagnosed with keratoconus and those with glaucoma. Keratoconus is a medical condition in which the clear tissue on the front of the eye (the cornea) bulges outward. Glaucoma is a medical condition in which the optic nerve, which is in the back of the eye, is damaged and can lead to blindness. This study will examine the response of the lamina cribrosa to an increase in eye pressure in human eyes in order to better understand the process that leads to glaucoma. The study is sponsored by the National Institute of Health (NIH).

We are inviting you to consider participating in this research because you are either a patient who has been diagnosed with keratoconus or with glaucoma.

3. How long will I be in the study? How many other people will be in the study?

This study will only require a single visit to complete all testing, although if testing time is cut short, it could require a single subsequent visit. We seek to enroll 230 participants of both genders ages of 18 and older (115 people with keratoconus and 115 people with glaucoma).

This study will be an out-patient study. Potential participants will be approached at Bellevue Hospital Ophthalmology clinic located at 462 1st Avenue, New York, NY 10016 or NYU Langone Medical Center Ophthalmology Faculty Group Practice located at 222 East 41st Street, New York, NY 10017. Study testing will be completed at NYU Langone Medical Center Ophthalmology Faculty Group Practice.

4. What will I be asked to do in the study?

Before any research procedures are performed, you will be asked to read and sign this consent form. If you agree to be part of this study, the following will happen:

- We will collect the following data from your routine eye exam, which is done regardless of your participation in this study:
    - We will review your past and current medical history,
    - We will review your family history,
    - Your eyes will be examined by your doctor and will include,
        - measurements of your visual acuity (how well you can see different sized letters on a chart),
        - intraocular pressure measurement (taken by very lightly touching your numbed eye),
        - slit lamp examination (when the doctor uses magnification to look directly at all of the different parts of your eye),
        - before and after pupil dilation (enlargement),
        - and axial length measurement (to see what the overall shape of your eyeball looks like)
        - A dilating drop may be used to enlarge your pupil for better results. This portion of the exam will take about 30 minutes.
    - We will conduct a test of your peripheral vision (visual field). In this test, you will be asked to sit at a machine and press a button when you see a light spot, which will be repeatedly presented to different regions within your visual field,
    - We will use a special camera called Pentacam to take a picture of your cornea (the clear tissue in front of your eye). This enables us to make a topographical map of your cornea,
    - A small, painless puff of air will be blown onto your eye to make sure your cornea is not too stiff
    - High-quality images of your eyes will be taken using Optical Coherence Tomography (OCT). The OCT shines a beam of low-powered light onto the eye, which is reflected back to the OCT and allows examination of different parts of the eye.
- In total, this could take approximately 2 hours

If you meet the criteria based on the eye exam, you will continue with the experimental portion of the research study.

Eye pressure will be measured as routinely done during eye examinations. Then we will use a device that pushes on your eye to increase the pressure in your eye. We will measure the pressure in your eye to see how much weight it takes to increase your eye pressure. Then you will wait for 20 minutes before being scanned with Optical Coherence Tomography (OCT) and Multimodal OCT. The order of the scanning will be randomized (determined by chance).

All these devices are approved by the US Food and Drug Administration (FDA) for scanning the eye except for some of the OCT devices and the Multimodal OCT, which do not cause any present or possible serious risk to your health, your safety, or your welfare. An image of your eye will be taken first with no pressure applied to your eye, two more images will be taken with pressure on your eye and a final scan will be taken with no pressure applied to your eye. The pressure will be applied to your eye for no longer than 2 minutes, during which the images will be taken. The total time of the scanning procedure will last approximately 10-15 minutes. This procedure will be repeated until scanning with all the devices is completed.

5. What are the possible risks or discomforts?

There are a number of possible risks, side effects, and discomforts associated with participation in this study. As with any investigational study, there may be risks of adverse events or side effects that are currently unknown and it is possible that certain unknown risks could be serious.

RISK OF INCREASED EYE PRESSURE
While increasing eye pressure may cause damage to the nerve tissue, the amount of force we are using and the length of time we are applying it in our study has been safely used previously and is not expected to cause any short or long-term damage. Some surgical procedures that are routinely used and are FDA-approved include longer and significantly higher increase of the eye pressure. The long-term evaluation of such procedures do not show any evidence of long-term nerve tissue damage.

RISK OF USE OF DEVICE FOR ELEVATING EYE PRESSSURE
Scratches to the cornea: the device we use is approved by the FDA and was designed with a smooth curved surface to minimize the possibility of corneal touch. The expected risk is less than 1 time in 100 people.

Infection: the device that touches your eye will be thoroughly cleaned with alcohol before every examination. The expected risk is less than 1 time in 100 people.

RISK OF THE OCT DEVICE
None of the research devices will physically touch your eye. There is no known risk for repeating OCT scans multiple times or on different days. You may have discomfort from holding still during scanning procedures or experience temporary color change and/or blurry vision after the scanning, which is common and expected to disappear within a few minutes. No pain or stress is expected because of these imaging procedures.

To reduce the possibility of eye infection, all exposed surfaces near your eye, as well as the chin and forehead rest of the instrument, will be cleaned with alcohol before you are examined. The risk of infection is less than 1 time in 100 people.

RISK OF EYE DROPS

All drops used in this study are FDA approved. Phenylephrine hydrochloride and tropicamide are common and widely used pupil dilating drops used for ophthalmic examinations. There is a risk of blurred vision and difficulty in near vision operation (e.g., reading and writing), which is common. The effects of the dilating drops will disappear within 3-4 hours after instillation. You may be asked to remain in the clinic in the event that you experience blurred vision and do not have an accompanying person. Dilation may cause your eye pressure to increase or the possibility of an acute angle-closure glaucoma attack, which happens in a rare configuration of the eyes. If either should occur, you will be treated immediately with eye drops at no cost.

OTHER RISKS
You may have discomfort from holding still during scanning procedures or experience temporary color change and/or blurry vision; this is common, happening as often as 10 times in a 100. No pain or stress is expected because of these imaging procedures. To reduce the possibility of eye infection, all exposed surfaces near your eye, as well as the chin rest of the instrument, will be cleaned with alcohol before you are examined. The risk for infection happens in less than 1 time in 100 people.

If we learn of any new information about study risks that could cause you to change your mind about continuing to participate, we will notify you promptly.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you.
This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You will not receive any direct benefit by participating in this research. However, if we find that the lamina cribrosa in subjects with keratoconus and those with glaucoma does react differently to increasing eye pressure, then this could help in better understanding the process that leads to the development of glaucoma. Therefore, participation may help others in the future.

8. What other choices do I have if I do not participate?

You do not have to participate in this study in order to undergo an ophthalmic evaluation using the devices and procedures. NYU's Department of Ophthalmology includes Pentacam, ORA and OCT as part of a standard ophthalmic evaluation. Pentacam is a special camera that takes pictures of your cornea so that we can make a map of the surface. ORA is another type of camera that allows us to see the surface of your eye. OCT is a camera that shines a very temporary light in your eye and allows us to take a picture of the surfaces in the back of your eye. Patients with glaucoma undergo imaging with OCT, while patients with keratoconus are evaluated with Pentacam and ORA. You may discuss alternative tests with your physician

If you are a student, resident, or employee of NYU Langone Health and its affiliates, your decision to participate, decline participation, or withdraw from the study will have no impact on your employment, academic standing, or grades. Record of the participation cannot be linked to an academic record. You are free to choose not to participate in the study.

9. Will I be paid for being in this study?

At the completion of the testing, you will receive $30 to compensate you for your time.
You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Dr. Chaim Wollstein at 929-455-5530.

10. Will I have to pay for anything?

All study related procedures will be at no cost to you or your insurance.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

If you withdraw from the study, no more information will be collected from you. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, ophthalmic evaluations, and imaging used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: *National Institute of Health*
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at *Bellevue Hospital.*
- Zeiss (the company providing the PLEX Elite 9000, swept-source OCT) and its affiliated companies and subcontractors
- Members of the ANGI Network (a network of leading clinicians and research institutions, hospitals, universities and other academic institutions around the world focused on the diagnosis and treatment of eye diseases (“Members”) who use the PLEX Elite ocular imaging device).

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

14. Financial Disclosure

The NYU School of Medicine maintains a financial disclosure process by which researchers must disclose any personal financial interests that may be related to the research.

Drs. Gadi Wollstein, Joel Schuman, and Hiroshi Ishikawa, research study doctors, are co-inventors of an optical coherence tomography (OCT) assessment system used in this study. Dr. Schuman also receives consulting payments from Carl Zeiss Meditec, Inc., a company that is licensing the related OCT intellectual property. Given these interests, Drs. Wollstein, Schuman, and Ishikawa could potentially benefit from the outcomes of this research.

The NYU Langone Conflicts of Interest Office (CIMU) has reviewed the researchers' financial interests and approved a written plan to monitor these interests for the duration of the study.

The NYU School of Medicine Institutional Review Board was informed of the CIMU determination. If you would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-263-4489.

15. Optional permission for future use

NYU Langone Health would also like to store, use, and share your health information from this study in research databases or registries to be considered as a candidate for participation in future research conducted by NYU Langone Health or its research partners. If you will be identified as a potential candidate for other research, a representative of that research team will discuss with you that possibility of joining that project. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYU Langone Health will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future consideration for research conducted by NYU Langone Health or its research partners.

_____
Subject Initials

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research

studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial 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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date