Official Title:	A Single-Center Proof Of Concept Study of a Novel Comfortable and Stabilizing Chin & Forehead Rest Attachment for Slit Lamp Configuration Devices
NCT Number:	NCT05686421
Study Number:	22-01420
Document Type:	Informed Consent Form
Date of the Document:	• April 11, 2023

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	**A Single-Center Proof of Concept Study of a Novel Comfortable & Stabilizing Chin & Forehead Rest Attachment for Slit Lamp Configuration Devices** Study Number: s22-01420
Principal Investigator:	Gadi Wollstein, MD Department of Ophthalmology NYU Langone Eye Center 222 East 41st St, Room 476 929-455-5530
Emergency Contact:	Gadi Wollstein, MD 929-455-5530

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?

Currently in Ophthalmological (Eye doctor’s) Offices, patients that are being imaged on optical coherence tomography (OCT) devices, used to take images of your retina, often do not have a comfortable patient experience. They tend to move away from the device in order to stretch every so often and oftentimes complain about it. This adds additional time to the imaging process, thereby extending the wait time for the following patients. Furthermore, due to the lack of ability to adjust the chin and forehead rest components to each individual patient’s size, the patients tend to move around quite a bit which both lengthens the time, as previously mentioned, as well as increases the likelihood of artifacts, which lead to the misdiagnosis of Glaucoma, a group of diseases that can cause vision loss and blindness.

Therefore, we are conducting research to evaluate an extendable and comfortable chin and forehead rest, which is patent-pending and considered to be experimental because it is not Food and Drug Administration (FDA) approved for clinical use. With this new device, we hope to minimize the potential

for patients to be misdiagnosed or undiagnosed with ocular (eye) diseases as a result of patient discomfort induced movement and subsequent diagnostic testing artifacts.

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

We seek to enroll 150 total subjects including healthy volunteers and subjects that have an existing eye disease such as glaucoma, age-related macular degeneration, diabetic retinopathy, macular edema, and other pathologies. The study duration will be a one-time imaging session. There will be no follow-up period. Your study visit will be at NYU Langone Eye Center located at 222 East 41st St, New York, NY 10017.

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

As part of this study, we will review your past and current medical history, you will have your routine eye examination. . Before you are imaged, we will measure the length of your face to determine if you are eligible for the study. If you are eligible, we will scan your eye with OCT, which is a device that takes high-quality images of the eye. 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. Before you are imaged, we will measure the length of your face to determine if you are eligible for the study. You will be imaged on two separate devices, once with the experimental device and once without. Before and after being imaged, a survey about your experience will be administered. If you choose to participate in this study, your time for the examination using both chin and head rest devices will be approximately twice as much time as is typically required in clinical practice (60 minutes vs. 30 minutes). A dilating drop may be used to enlarge your pupil for better results.

Any identifiable private information collected and/or used for the purposes of this research will not be used for future research studies.

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 THE OCT DEVICE
Imaging will be performed using commercial (FDA approved) and non-commercial (non-FDA approved) OCT imaging instruments. All devices are subject to standard medical regulatory and safety requirements and adhere to the American National Standards Institute safety standards for the use and exposure to lasers. There is no known risk for repeating OCT scans multiple times on the same day or on different days.

None of the research devices will physically touch your eye. 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 low.

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.

RISK OF EYE DROPS

Phenylephrine Hydrochloride or 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.

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, we hope that, in the future, other people might benefit from this study because the information gained will help provide a more comfortable experience for patients being imaged by ophthalmic devices in the clinic.

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

You are free to choose not to participate in the study. Your decision will not affect your care.

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

At the completion of the study visit, you will receive $20 to compensate you for your time.

You are required to track all payments made to you by NYU Langone Health 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. Financial Disclosure

The NYU Langone Health maintains a financial disclosure process by which researchers must disclose any personal financial interest that may be related to the research. One or more of the researchers involved this study, is an inventor of a patent that is owned by NYU and will be used to facilitate this study. As a result of the intellectual property rights, these researchers and NYU may benefit if the results of this study are favorable. If you would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4079.

12. 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 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.

13. 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 U.S. 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 FDA, or other body responsible for monitoring the safety of the study has decided to stop the study.

It is your choice to be in this study. No one can force you to be in the study. You can leave the study at any time. Leaving the study will not affect the care you receive. You will still receive the same high level expert care you were receiving at NYU School of Medicine before you became a part of the study.

14. 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 information about the investigational device 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 research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Eye Institute (NEI)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others 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.

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.

16. Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because the images are being taken on research prototypes and not diagnostic devices. Therefore, the images are to be used for research purposes only and are not part of your medical history and clinical care.

Results that will not be placed in the medical record: Images taken on OCT prototype devices.

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

The IRB reviews all human research studies – including this study. The IRB protects 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 School of Medicine's IRB is made up of:

- Doctors
- Nurses
- Non-scientists
- People from the Community

You may contact the IRB if you have any questions about your rights as a subject, if you think you are not treated fairly or if you have any questions about this research study. The NYU IRB Office number is (212) 263-4110.

18. 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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 Process for Non-English-Speaking Subjects (using a translated consent form OR "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