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:	Study Protocol and Statistical Analysis Plan
Date of the Document:	• April 11, 2023

A SINGLE-CENTER PROOF OF CONCEPT STUDY OF A NOVEL COMFORTABLE AND STABILIZING CHIN & FOREHEAD REST ATTACHMENT FOR SLIT LAMP CONFIGURATION DEVICES

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NYULMC Study Number:	*S22-01420*
Study Product:	Comfortable chin and forehead rest that can be adjusted to fit each individual's size.

Initial version: 12/20/2022
Version 2.0: 03/09/2023
Version 3.0: **03/31/2023**

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), 21 CFR Parts 50, 56, 312, and 812 as applicable, any other applicable US government research regulations, and institutional research policies and procedures. The International Conference on Harmonisation ("ICH") Guideline for Good Clinical Practice ("GCP") (sometimes referred to as "ICH-GCP" or "E6") will be applied only to the extent that it is compatible with FDA and DHHS regulations. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

ABS	Acrylonitrile butadiene styrene
AE	Adverse Event/Adverse Experience
C	OCT Imaging Device C, Conventional Device
CFR	Code of Federal Regulations
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
FFR	Federal Financial Report
FWA	Federal wide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
ISM	Independent Safety Monitor
MOP	Manual of Procedures
N	OCT Imaging Device N, Novel Device
NIH	National Institutes of Health
OCT	Optical Coherence Tomography
OD	Oculus Dextrus
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
ONG	Optic Nerve Head
OS	Oculus Sinister
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure

UP	Unanticipated Problems
US	United States

Protocol Summary

Title	Comfortable and Stabilizing Chin & Forehead Rest Attachment for Slit Lamp Configurations
Short Title	Invention Study
Brief Summary	Cohort will consist of 150 subjects consisting of those that are healthy or have an existing eye disease. Subjects will be imaged on two OCT devices: device N, invention attached to the device and device C, the standard conventional device. The Imager will time multiple durations, one of them which will act to evaluate the number of motion artifacts that arise due to both the instability and lack of comfort the patient is experiencing in that particular moment. Following the imaging session, subject will be asked which device was more comfortable.
Phase	*NA*
Objectives	The primary objective is to ascertain that the OCT Imaging device with the invention attached provides a more comfortable experience for the subject. While the secondary objective is to reduce the time it takes for the system to account for the number of motion artifacts.
Methodology	Randomized
Study Duration	Until target number of subjects is reached
Participant Duration	One clinic visit
Duration of IP administration	One clinic visit
Study Sites	NYU Department of Ophthalmology
Number of participants	150 subjects
Description of Study Agent/Procedure	Comfortable chin and forehead rest that can be adjusted to fit each individual's size.
Statistical Analysis	Descriptive statistics for continuous variables and categorical data, presented using frequency counts and percentages will be used for group and device comparison. Patient experience will be assessed using two-sided exact test of proportion. Comfort levels of each device will be compared using t test. Linear mixed effect models will be utilized to compare the time duration while accounting for inter-eyes correlations.

Schematic of Study Design

Screening Period

- Total n=150
- Obtain informed consent
- Screen potential subjects by inclusion and exclusion criteria
- Obtain history, document

Day of Imaging

1. **Randomize Order of Devices**

- Provide clinic with 150 envelopes in which they are assigned with instructions regarding which device and eye the Imager should begin with (C/N & OS/OD)

2. **Study Intervention**

- Measure the length of the subject's face
- Provide subject with questionnaire containing the following
    - Are you feeling well?
    - Are you feeling tired today?
    - Are you uncomfortable?
- Scans should be taken on device C and N on each eye
    -

3. **End of Study Assessments**

- Directly following the imaging session, questionnaire including the following should be provided to the subject:
    - Which device was more comfortable?
    - On a scale of 0-5, please rate the comfort level for each device

1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Currently in Ophthalmological Offices, patients that are being imaged on OCT devices 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.[1]This is a catastrophic pitfall as 3 million Americans have Glaucoma, which is the "second leading cause of blindness worldwide[2]. Additionally, there are 43 million people worldwide that suffer from blindness and 77% of those cases could have possibly been prevented by reducing the number of artifacts in their scans.[3] To summarize, the purpose of this invention is to solve the problem in which patients are potentially being misdiagnosed or undiagnosed with ocular diseases as a result of patient discomfort induced movement and subsequent diagnostic testing artifacts which could prevent an efficient intervention to be enacted thereby reducing the patient's chances of suffering from a debilitating eye disease.

2.2 Name and Description of the Investigational Agent

The extendable and comfortable chin and forehead rest is a patent pending device (Atty. Dkt. No.: 046434-0793). The invention consists of six components: the chin rest, mount and its attachment and the forehead rest, mount and its corresponding attachment.

When designing this product, various constraints were considered: the need to easily and efficiently sterilize the components between patients, the material being biocompatible (in terms of it not having any adverse effects on the patient due to its properties), the materials selected and structure designed needed to prove to be durable enough to withstand the weight of a person's head, aid in providing the patient with a comfortable resting position, and, lastly, to stabilize the patient's head properly.

Table 1 shown below provides the Bill of Materials for the Chin rest. It includes the material used, quantity along with a description of the component.

Part	**Qty.**	**Description**	**Material**
Chin rest Base Front	1	patient rests chin on	ABS/ Biomed Back Resin
Chin rest Base Back	1	2 threaded holes for knobs	Steel
Rotary Shaft	2	extension mechanism	316 Stainless Steel
Bearing	4	reduces friction along shaft	841 Bronze
Head Thumb Screw	2	locking mechanism	Steel low profile

Table 1: Chin Rest - Bill of Materials

The mechanism used to adjust the chin rest for each individual patient are two rotary shafts that the chin rest can slide along to be extended as needed and locked in place by two head thumb screws (this design can be upgraded to operate via a remote control). Four bearings are also incorporated into the design in order to reduce friction caused by the movement of the shafts within the extrusions.

Lastly, a cushion is used for the rests, which provides the essential component of comfort enhancing the patient's overall experience.

In order to incorporate the chin rest into the existing ophthalmic devices on the market, a mount and attachment were designed. The mount functions as a stage for the chin rest and can be adjusted, by use of grippers, to fit the variable length of the chin rest for each patient's appropriate dimensions. The mount is then connected to the attachment via a ball joint. This provides the ability to make additional adjustments per patient as it can move in the y and z directions as well, which will ultimately maximize the stability of the patient's head while being imaged, as well as provide a more comfortable and positive patient experience. Finally, in order to connect the chin rest and mount to the devices, a simple clamping mechanism is utilized, which is designed for each device.

In Table 2 below, the bill of materials is provided for the mount and attachment for the chin rest.

Part	**Qty.**	**Description**	**Material**
Clamp (male)	1	half of clamp (specific to each device)	ABS
Clamp (female)	1	half of clamp (specific to each device)	ABS
Lock - Threaded Rod	1	locking mechanism for attachment to device	Stainless Steel
Slide Lock	1	locking mechanism for extending the mount	Stainless Steel
Threaded Pin	1	connects male and female clamp	Stainless Steel
Edge Adjuster	4	adjusts mount size according to chin rest extension	ABS

Table 2: Mount & Attachment - Bill of Materials

The overall mass and weight of the chin rest, mount and attachment is approximately .249 kg and 2.44 N.

The forehead rest component of the invention was designed with similar considerations and constraints in mind. One additional constraint when designing the adjusting mechanism for different size patient heads was to ensure that while adjusting the forehead rest no part of the patient's skin on their forehead would be pinched as a result of the movement of the parts relative to one another.

The overall design of the forehead rest includes multiple mechanisms. Specifically, two mechanisms that are present to adjust for each patient include:
1) the cylinders protruding from the side of the forehead rest
2) the quick release strap on the buckle located on the front and center of the forehead rest.
The cylinders are designed to fit into a slot clamped to the ophthalmic device and have a dual purpose in which it is used to account for adjustments needed to move the patient relative to the device, as well as mounting the forehead rest to the ophthalmic devices. Similarly, the quick release buckle is used to account for each individual patient's head size which can be done by tightening or loosening the strap accordingly. As the forehead rest is composed of the male and female parts, the male part would have the ability to move linearly relative to the female part.

The forehead rest would be made almost exclusively from ABS, not accounting for the parts sourced off the shelf (quick release buckle, screws, etc.) and the silicone cushion covering.

2.2.1 Preclinical Data

There is no available preclinical research data on the investigational product.

2.2.2 Clinical Data to Date

There is no available clinical research data to date on the investigational product.

2.3 Rationale

This study primarily focuses on increasing the comfort for each patient's experience as well as reducing motion artifacts by improving the former, as well as stabilizing the patient's head, accomplished by adjusting the chin and forehead rest for each individual patient. The cohort will consist of a total of 90 subjects consisting of subjects that are both healthy and have an existing eye disease, as commonly observed in ophthalmology outpatient offices.

In order for certain limitations to not affect the validity of the results, various aspects of the trial will be randomized. This includes, but is not limited to, the order in which a patient will begin being imaged on either device C/N and which eye, OS/OD the Imager will scan first. This can help account for parameters including whether the time it takes to image the patient and/or level of comfort is affected as a result of their degree of alertness, energy level, how they are feeling on that particular day, etc.

2.4 Potential Risks & Benefits

2.4.1 Known Potential Risks and Benefits

There is a risk of blurred vision and difficulty in near vision operation (e.g., reading and writing), which is common, due to the use of the dilating drops Phenylephrine Hydrochloride or Tropicamide. The effects of these drops will disappear within 3-4 hours after instillation. The participant may be asked to remain in the clinic in the event that they experience blurred vision and do not have an accompanying person.

Pupil dilation may cause an increase in eye pressure or the possibility of an angle-closure event,

which happens in a rare configuration of the eyes. All subjects will be examined clinically Before dilating drops are instilled to identify eyes at risk, in which case no dilation drops will be used. If either of these risks should occur, the subject will be treated immediately with eye drops at no cost.

Ophthalmologic OCT imaging is performed in a non-contact fashion, so there is minimal risk of infection to the participant. To reduce the possibility of eye infection, all exposed surfaces near the eye, as well as the chin rest and forehead rest of the instrument, will be cleaned with alcohol before participants are examined. The risk of infection is low.

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 cumulative risk for repeating OCT scans multiple times on the same day or on different days.

Participants will receive no direct benefit by participating in this study. However, there may be societal benefit related to generalizable knowledge gained by doing this study.

3 Objectives and Purpose

3.1 Primary Objective

To assess the level of comfort provided by the chin and forehead rest attachment invention when coupled with existing imaging devices, i.e. OCT and Slit Lamp.

3.2 Secondary Objectives

To evaluate the time duration that is needed to adjust for the number of motion artifacts present while using the novel chin and forehead rest attachment when coupled with existing imaging devices, i.e. OCT and Slit Lamp.

4 Study Design and Endpoints

4.1 Description of Study Design

This is a randomized clinical trials study that includes two arms: experimental and control. The purpose of these arms is to compare the medical outcomes in terms of the subject's level of comfort as well as reducing the amount of motion artifacts. Subjects that are willing to participate will be required to participate in both arms.

Because the study design follows routine standard of care, there are no specific safety end points related to this project.

4.2 Study Endpoints

4.2.1 Primary Study Endpoints

In order to achieve the primary objective, proving that the level of comfort of the chin and forehead rest invention attached to the existing OCT imaging devices, as opposed to the conventional existing headframes is of a higher caliber, the primary endpoint will be achieved by providing the subject with a questionnaire directly after being imaged and asking two questions: which device, C/N, provided a more comfortable experience, and on a scale of 0-5 to rate the level of comfort, as a result of the headframe, i.e. chin and forehead rest, that the subject experienced while being imaged on either device C/N.

4.2.2 Secondary Study Endpoints

A secondary objective includes evaluating various time durations while a patient is being imaged to determine whether the amount of motion artifacts are in fact being reduced by implementing the invention to existing devices. In one of the standard clinical OCT imaging devices, the Cirrus OCT, there is an eye tracking mode that can be activated whilst imaging a patient. This feature selects a specific location within the eye and will constantly adjust, i.e. track, for the fine fixation adjustments that occur when a patient's eye is moving very slightly. Therefore, in order to view whether there are a higher number of motion artifacts found in one image versus another, the Imager can time the duration it takes from the moment that they click "acquire", to when the progress bar is full. This is because the more time it takes for the system to fully acquire an image it directly correlates to how still the subject's eye is. Additionally, the data acquisition time can also be affected by whether the Imager is able to acquire a clear fundus photo, i.e. when there are no media opacities as well as if the Imager properly corrects for the refractive error.

5 Study Enrollment and Withdrawal

We aim to enroll 150 total subjects including healthy volunteers and subjects that have an existing eye disease including, but not limited to, glaucoma, AMD, DR, and CSCR. The site can actively enroll new subjects and these subjects will be are continuously followed in their institute. The total NYU cohort will include 150 healthy subjects as well as any eye related disease suspect subjects. There will be no enrollment restrictions based on gender, ethnic origin or HIV status and the study population will reflect the demographics of NYU Department of Ophthalmology. Subjects from clinical groups will participate in all applicable sub-studies of the protocol.

Subjects will be included in both groups, labelled as either Group 1 (Novel) or Group 2 (Conventional). Both groups will include subjects that are identified with glaucoma, age related macular degeneration, diabetic retinopathy, and central serous chorioretinopathy or any other eye related disease as well as healthy volunteers that are recruited from the clinic that undergo the clinical examination as part of their routine clinical management and healthy volunteers that are invited to the clinic to undergo the clinical examination for the purpose of the study.

5.1 Inclusion Criteria

Candidates must meet the first inclusion criteria and either one of the last two criteria in order to participate in the study.

- Ages 18 and older
- Healthy volunteers
- AMD, diabetic retinopathy, central serous chorioretinopathy, and/or glaucoma or glaucoma suspects or any other suspected eye disease
- Face length of less than or equal to 6.900 inches

Group-Specific Inclusion Criteria

There are no group-specific inclusion criteria for subjects with AMD, diabetic retinopathy, and central serous chorioretinopathy.

Healthy

– A normal clinical ophthalmic examination.

Primary Open Angle Glaucoma (POAG)

– Clinical characteristics of glaucoma: optic nerve head (ONH) abnormalities: global rim thinning, rim notch, or disc hemorrhage; retinal nerve fiber layer (RNFL) defect.
– Typical glaucomatous field loss in reliable VF, reproducible glaucoma hemifield tests labeled outside normal limits on at least two consecutive tests.
– Good quality (adequate signal strength ≥ 6/10, without segmentation algorithm failure and motion artifacts > 1 vessel diameter) RNFL and GCIPL OCT, labeled outside normal limits with typical glaucomatous RNFL and GCIL thinning.

Normal Tension Glaucoma (NTG)

– Identical to POAG criteria with IOP recorded at ≤ 21 mmHg at any time point.

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Any medical treatment (e.g., chronic corticosteroid, hydroxychloroquine, chloroquine, thioridazine, canthaxanthine) or conditions that affect VF (e.g., stroke) and retinal thickness other than glaucoma.
2. Face length of over 6.900 inches

5.3 Strategies for Recruitment and Retention

Healthy volunteers, and patients with glaucoma, AMD, DR, and/or CSCR as well as any other eye disease will be enrolled consecutively from NYU Department of Ophthalmology from the investigators and the research team's clinics, recruitment telephone script and via IRB-approved messaging through the MyChart portal in Epic. The study does not require a screening procedure, and all qualified subjects will be offered to participate in the study. Potential candidates will be informed by their clinician or a clinical coordinator from the research team. The participants will receive a comprehensive explanation about the study, risks and benefits and will be encouraged to ask questions related to the study. We will emphasize that participation is voluntary. Documentation of the informed consent process will be used to ensure that the appropriate questions have been asked to the perspective participant. Only study personnel will conduct consenting process. For candidates who are not fluent in English, NYU translation services will be used to ensure that the candidate fully understands the study and the consent. We anticipate on encountering subjects that are fluent in a language other than English. Therefore, the informed consent will be translated in the following languages following initial approval: Spanish and Korean. For an unexpected enrollment (subject doesn't speak English, Spanish, Korean but meets all inclusion criteria), we will use the short form with an interpreter and then will have the ICF translated in the subject's language and submitted via modification to the IRB to allow for any reconsenting in the future if necessary as well as to enroll other subjects who speak this particular language.

Participation in the study and data collection will be possible only after subjects have signed consent.

5.3.1 Use of DataCore/Epic Information for Recruitment Purposes

This study will utilize EPIC to identify subjects. Data and records will be sourced for EPIC. Data will be gathered upon request by DataCore and be used for case identification as well as collecting information. The data team will search EPIC weekly. Medical records will be screened by initially filtering for all patients that are diagnosed as healthy, primary open angel glaucoma, and normal tension glaucoma from 2022-2026. Identified patients will then have their electronic medical records reviewed based on the protocol's outlined inclusion and exclusion criteria. Protected health information that will be used during this study includes patient name, zip code, date of birth, and specific date of birth for patients over 90 years in stead of recording their as "90 or older". Patient names will temporarily be used while determining eligibility but will not be used for data analysis. Date of birth and specific date of birth for patients over 90 years instead of recording their age as "90 or older" will be used to determine eligibility and to group patients by age during data analysis. Data will be collected and recorded using Microsoft Excel. Data will be stored within an NYULH MCIT-managed network shared drive and be subsequently deleted from the shared drive upon completion of the study. Data will be accessible to the principal investigator, sub-investigator, coordinators and study team members.

Data Points and PHI used in EPIC search:

- Age
- Name
- Date of birth
- Diagnosis (Healthy, Primary Open Angel Glaucoma, Normal tension glaucoma, AMD, diabetic retinopathy, central serous chorioretinopathy, and/or glaucoma or glaucoma suspects or any other suspected eye disease)

To minimize risks to subjects and/or potential breach of confidentiality, only information required to answer the previously listed research objectives will be acquired. Additionally, any potential disclosure outside of research would not put subjects at risk or harm.

Any recruitment information sent by email will utilize Send Safe email.

Once potential subjects have been identified, the study team will notify the treating physician (TP) by email that they have patients eligible to participate as one of the following:

- Provide TP with a list, advertisement, letters or oral script to use when contacting potential subjects
- TP and Research PI send letter to all potential subjects (letter must have both TP and Research PI's name)
- TP agrees to permit study team to directly contact potential subjects on behalf of TP.
- TP has been notified that the study team will contact potential subjects directly, by letter, phone, email, or the MyChart portal etc.

The patients will be contacted either by MyChart, in-person during their clinic visit at the eye center or prior to their visit using a phone script (attached).

Once contact is made, approved recruitment language will be used to communicate the reason they are being contacted and subjects will be asked if they are interested in participating in this specific study. Should the potential subjects agree, the study team will provide the subjects with information regarding the next steps for participation.

If a subject requests information regarding opting out of further recruitment for all research, subjects will be directed to contact research-contact-optout@nyumc.org or 1-855-777-7858.

5.4 Data Storage and Confidentiality

Data collection is the responsibility of the study staff at the site under the supervison of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Confidentiality will be held in strict trust by the research team. Medical record review will be limited

to just the elements needed to complete the study. Information about individual subjects will not be shared with anyone outside of the study team.

Study data will be stored in Trialmaster used in the NYU Langone Health Department of Ophthalmology. Subject data will be stored until the completion of data analysis and will subsequently be removed from the shared drive upon completion.

5.5 Duration of Study Participation

Besides for the screening, which is discussed in the previous section, the duration of study participation is solely for the one-time imaging session, i.e. one day. There is also no follow-up period.

5.6 Total Number of Participants and Sites

Recruitment will end when approximately 150 participants are enrolled at NYUMC.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Subjects may withdraw, at any time, their consent for participation in this research study. Subjects who are unduly distressed and cannot complete the research requirements will be withdrawn from the study. Any identifiable research or medical information recorded for, or resulting from, subject participation in this research study prior to the date that subject formally withdrew consent may continue to be used and disclosed by the investigators for the purposes described above.

5.8 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Principal Investigator. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the IRB and/or FDA.

6 Study Agent (Study drug, device, biologic, vaccine etc.) and/or Procedural Intervention

6.1 Study Device Description

The device, chin and forehead rest, has its provisional patent currently filed to the USPTO.

Its constituent parts may include, but are not limited to other possible configurations as listed in the patent, and are described and can be seen in further details in the tables below.

Table 1 shown below provides the Bill of Materials for the Chin rest. It includes the material used, quantity along with a description of the component.

Part	Qty.	Description	Material
Chin rest Base Front	1	patient rests chin on	ABS/ Biomed Back Resin
Chin rest Base Back	1	2 threaded holes for knobs	Steel
Rotary Shaft	2	extension mechanism	316 Stainless Steel
Bearing	4	reduces friction along shaft	841 Bronze
Head Thumb Screw	2	locking mechanism	Steel low profile

Table 1: Chin Rest - Bill of Materials

In Table 2 below, the bill of materials is provided for the mount and attachment for the chin rest.

Part	Qty.	Description	Material
Clamp (male)	1	half of clamp (specific to each device)	ABS
Clamp (female)	1	half of clamp (specific to each device)	ABS
Lock - Threaded Rod	1	locking mechanism for attachment to device	Stainless Steel
Slide Lock	1	locking mechanism for extending the mount	Stainless Steel
Threaded Pin	1	connects male and female clamp	Stainless Steel
Edge Adjuster	4	adjusts mount size according to chin rest extension	ABS

Table 2: Mount & Attachment - Bill of Materials

A further description of the device and its potential configurations can be found in section 2.2 as well as the provisional patent application attached.

The device is not a significant risk device as it is solely being used to stabilize the subject's head. The materials in contact with the patient are biocompatible and will also be sterilized and sanitized accordingly. The device does not meet the 4 criteria for Significant Risk device in accordance with 21CRF 812.3(m), because (1) it is not intended as an implant (2) It Is not purported or represented to be for a use in supporting or sustaining human life (3) It Is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; (4) Does not

Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. The results of the imaging using the investigational device will not be used to make a clinical diagnosis or guide care.

6.1.1 Acquisition

Silicone components of the device will be supplied by the manufacturer, Zetar and will be shipped directly to the Principal Investigator in the NYU Ophthalmology Clinic. Any components that are made from some form of metal will be purchased and sourced directly from the mainstream hardware suppliers, such as McMaster Carr. The remainder of parts will be produced and acquired by the hospital makerspace or machine shop.

6.1.2 Formulation, Appearance, Packaging, and Labeling

The device is comprised of various components. Depending on the complexity and availability for these components to be sourced off the shelf the remainder will either be manufactured in house by the mechanical engineers and machinists in NYU and the silicone related parts will be manufactured by Zetar, a Silicone manufacturing factory in China. All components will be sourced with the constraint of each material being biocompatible as to not cause any irritation to the subjects when they are resting their head on the chin and forehead rest.

6.1.3 Product Storage and Stability

The device storage requirements include:

1. -20 to 80 degrees Celsius, as outside that range the ABS parts mechanical properties vary with temperature
2. Avoid being in areas containing a high humidity as that can increase the rate of corrosion of the stainless steel components
3. Secured in a container as to avoid contamination of the components

6.1.4 Preparation

Preparation of the device includes solely the mounting of the device to the existing OCT Imaging devices one time before a day of imaging subjects by the study staff.

The instructions are as follows:

1. Remove the device from the container and calibrate the device by measuring the length of the subject's face.
2. Attach the chinrest mount to the OCT Imaging devices by placing the top and bottom parts of the invention, shown in the provisional patent attached, to the existing chinrest of the imaging device
3. Click into place the right and left pieces into the extruded holes in the top and bottom parts of the attachment, shown in the second configuration of the chinrest mount in the provisional patent
4. Push the ball joint section of the plate into one of the two grooved holes on the top of the attachment, either the right or left one depending on whether the OD/OS will be imaged first
5. Wipe the exposed parts of the chinrest with an alcohol swab
6. Secure the forehead rest attachment to the existing Cirrus device by sliding the clip down the front of the existing forehead rest
7. Wipe the exposed parts of the forehead rest with an alcohol swab

6.1.5 Administration

The order in which a subject will be imaged on either OCT imaging device C/N and whether the Imager will begin with either the OD/OS eye will be randomized. This will be done by providing the NYU Ophthalmology Clinic with a total of 90 envelopes that the Imager will choose from a mixed pile in which they will be evenly divided with a message to begin with device C/N and to begin with eye OD/OS.

The Standard Operating Procedure as to how to operate the novel device for imaging a subject can be seen below:

1. Sanitize chin and forehead rest
2. Seat subject by device
3. Move chinrest to either OD/OS
    a. Slide chinrest to either right/left side
4. Size chinrest
    a. Subject should place their chin in the rest and technician should either pull apart/push together the chin rest to either make it larger/smaller to fit the patient
5. Size mount of chinrest
    a. Pull apart the mount easily to allow for the chinrest's length to be extended
6. Lock extension
    a. Rotate knobs on both sides
7. Find correct/comfortable angular position of the chinrest
    a. Push/move chinrest to position that it is comfortable i.e. not protruding into subject's neck and subject feels relaxed
8. Lock rotation
    a. Tighten the bolt placed around the ball joint
9. Subject should rest forehead against the rest
10. Technician /imager should check if subject has to be adjusted closer to the device (based on the image from the device)
    a. push/pull forehead rest by side of device so it will be adjusted along the grooved slot
11. Size forehead rest
    a. tighten/loosen the strap on the side of the forehead rest to either make it smaller/larger for the patient (it will automatically lock into place)
12. Check if subject is comfortable, adjust if need be
13. Image subject according to scan protocol

6.1.6 Duration of Therapy

The duration of therapy includes one imaging session in which the subject is imaged on both device A and B for both eyes and has 1 scan of their Macula and 1 scan of their ONH acquired.

For the second objective, an evaluable participant should be consistent with Section 10, Statistical Considerations and/or Statistical Analysis Plan (SAP) which will include the minimum time duration it can take for an image to be acquired which can provide a result yielding in a statistically significant value.

6.1.7 Device Specific Considerations

The device is comprised of multiple assemblies:

1. Chinrest Assembly
    a. chinrest
    b. mount
    c. attachment to existing device
2. Forehead rest Assembly
    a. forehead rest
    b. attachment to existing device

While the shapes of the aforementioned assemblies are complex, their overall dimensions are in IPS unit system and have a tolerance of .01", unless stated otherwise, are as follows:

1.
    a. 4.40" x 3.40" x 0.77"
    b. 3.50" x 2.0" x 0.38"

c. 5.67” x 1.22” x 1.65”

2.

a. 5.0” x 2.10” x 0.61”
b. 5.0” x 1.80” x 0.25”

Furthermore, the frequency of exposure will be for just one imaging session.

7 Study Procedures and Schedule

7.1 Study Procedures/Evaluations

7.1.1 Standard of Care Study Procedures

- Medical history will be obtained from medical records
- Medication history should include medications currently being taken

7.2 Imaging Procedures

- Chin and forehead rest will be adjusted for each individual subject by following the appropriate procedure, shown in standard operating procedure attached
- OCT Imaging should include for each eye
  - Acquisition of 1 image of the Macula
  - Acquisition of 1 image of the ONH
- Two separate questionnaires will be provided to the subject before and after being imaged

7.2.1 Clinical Laboratory Evaluations

Not applicable as no labs will be needs.

7.3 Concomitant Medications, Treatments, and Procedures

Not applicable.

8 Assessment of Safety

8.1 Safety, Adverse Events Risks and Discomforts

There is a risk of blurred vision and difficulty in near vision operation (e.g., reading and writing), which is common, due to the use of dilating drops. The effects of these drops will disappear within 3-4 hours after instillation. The participant may be asked to remain in the clinic in the event that they experience blurred vision and do not have an accompanying person.

Pupil dilation may cause an increase in eye pressure or the possibility of an angle-closure event, which happens in a rare configuration of the eyes. All subjects will be examined clinically
Before dilating drops are instilled to identify eyes at risk, in which case no dilation drops will be used. If either of these risks should occur, the subject will be treated immediately with eye drops at no cost.

Ophthalmologic OCT imaging is performed in a non-contact fashion, so there is minimal risk of infection to the participant. To reduce the possibility of eye infection, all exposed surfaces near the eye, as well as the chin rest and forehead rest of the instrument, will be cleaned with alcohol before participants are examined. The risk of infection is low.

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 cumulative risk for repeating OCT scans multiple times on the same day or on different days.

8.1.1 Adverse Event

The IRB and participants will be notified immediately of any new information, in regards to this study. Expected and serious adverse events that occur will be reported to the
IRB according to the IRB Reference Manual. Fatal or life-threatening adverse events with research intervention will be reported to the IRB within 24 hours of notice. If there is a major unresolved dispute between the research investigator and a research subject or between research investigators, a letter will be submitted to the IRB describing the dispute and identifying the parties involved.

All adverse events occurring during the study period will be recorded. At each contact with the participant, the investigator will seek information on adverse events by specific questioning and examination. Information on all adverse events will be recorded in the patient file immediately. The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that participation in the study is not the cause. Serious adverse events that are still ongoing at the end of the study period will be followed to determine the final outcome.

A review of the outcome and adverse event data will be monitored by the PI and sub-investigators to determine whether the study should be continued, should be changed, or should be terminated. A copy of the DSMB report will be submitted to the IRB at the time of renewal.

The PI will be ultimately responsibility for the data safety monitoring of the overall study. ADSMB will include the PI, sub-investigators and clinical coordinators in conjunction with a licensed ophthalmologist, Dr. Joel Schuman, who will meet once every two months to monitor cumulative data points such as patient questionnaire, data acquisition time, adverse events, serious adverse events, withdrawals, early terminations recruitment, retention, confidentiality and adherence to the study protocol. At the time of obtaining renewal approval from the IRB, a report indicating whether there is any change in the risk benefit considerations of the study will be submitted. There are no specific stopping rules for this study.

8.2 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor. All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate RF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. UPs will be recorded in the data collection system throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the IRB of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The IRB should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

8.2.1 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. The site investigator will report the UP to the IRB. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are SAEs will be reported to the IRB within a timeline that is in accordance with the policy of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within a timeline that is in accordance with the policy of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within a timeline that is in accordance with the policy of the IR's receipt of the report of the problem from the investigator.

9 Clinical Monitoring

Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

- Each clinical site will perform internal quality management of study conduct, data collection, documentation and completion. An individualized quality management plan will be developed to describe a site's quality management.

10 Statistical Considerations

10.1 Statistical Hypotheses

We hypothesize there will be a significant difference between the patient's experience in terms of comfort while being scanned using the attachment of the chin and forehead rest mounted on the existing ophthalmic devices. Additionally, we expect to see a significant improvement in time duration of adjusting motion artifacts.

10.2 Sample Size Determination

Let P1 be the proportion of patients who report improvement of comfort and then P0=1-P1 be the proportion of patients who report no difference between two devices. The primary outcome of interest is to see if P_1 is significantly bigger than 50% or not. With sample size of N=90 subjects, we will achieve 80% power to detect that P1 > 65.7% using a two-sided exact test of proportion with a significance level of 0.05. These results assume that the population proportion P1 under the null hypothesis is 50%.

10.3 Statistical Methods

Unless otherwise specified, descriptive statistics for continuous variables include the number of patients with data (N), mean, standard deviation (SD), median, minimum, and maximum. The same number of decimal places as in the observed value are presented when reporting median, minimum, and maximum; one more decimal place than in the observed value is presented when reporting mean and quartiles; and two more decimal places than in the observed value is presented when reporting SD.

Categorical data are presented using frequency counts and percentages. All percentages are rounded to one decimal place, unless otherwise specified. Percentages equal to 100 are presented as 100% and no percentages are presented for zero frequencies. Where individual variable values are missing, summaries of categorical data are based on reduced denominators (i.e., the denominators include only patients with available data) and the number of missing values is presented.

The improvement of patient's experience in terms of comfort will be assessed using two-sided exact test of proportion to compare P_1 and P_0. Further, the comfort levels of each device from all patients will be compared using t test. Linear mixed effect models will be utilized to compare the time duration of adjusting motion artifacts between two devices while accounting for inter-eyes correlations. The p values less than 0.05 will be considered as significant.

10 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial. It is acceptable to use CRFs as source documents. If this is the case, it should be stated in this section what data will be collected on CRFs and what data will be collected from other sources.

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is

left blank because the procedure was not done or the question was not asked, write “N/D”. If the item is not applicable to the individual case, write “N/A”. All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

11 Quality Assurance and Quality Control

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

Following written SOPs, the monitors will verify that the clinical trial is conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements (e.g., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP)).

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the study staff and inspection by local and regulatory authorities.

12 Ethics/Protection of Human Subjects

12.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

12.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

12.3 Informed Consent Process

12.3.1 Consent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study agent, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study product.

12.3.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their relatives or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A copy of the signed informed consent document will be stored in the subject's research record. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process (e.g. use of a translator, , consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

12.4 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the study staff.

The study monitor, other authorized representatives of the study staff, representatives of the IRB or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at NYU Langone Medical Center. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by NYU Langone Medical Center research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NYU Langone Medical Center.

To further protect the privacy of study participants, a Certificate of Confidentiality will be obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

13 Data Handling and Record Keeping

13.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) will be entered into Trialmaster, a 21 CFR Part 11-compliant data capture system managed by NYULH DataCore. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

13.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close-out, 5 years after final reporting/publication, or 2 years after the last approval of a marketing application is approved for the device for the indication for which it is being investigated or 2 years after the investigation is discontinued and FDA is notified if no application is to be filed or if the application has not been approved for such indication. No records will be destroyed without the written consent of the study staff, if applicable. It is the responsibility of the study staff to inform the investigator when these documents no longer need to be retained.

13.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site PI/study staff to use continuous vigilance to identify and report deviations within 1 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity.

All protocol deviations must be addressed in study source documents, reported to a specific NIH IC Program Official.

Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

13.4 Publication and Data Sharing Policy

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to

register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

FDAAA mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials":

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations of a product subject to FDA regulation;
- Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric post market surveillance studies.
- NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA.

14 Study Finances

14.1 Funding Source

Charges will be billed only for procedures performed as part of the subject's routine clinical care. All other costs will be charged to the grant funded by the NIH NEI-R01-EY013178.

14.2 Costs to the Participant

Subjects will not be required to pay for any associated costs resulting from this study.

14.3 Participant Reimbursements or Payments

All participating subjects will receive $20 as compensation for their time.

15 Interest Policy

The PI, Dr. Wollstein, has potential conflicts of interest with this project. NYU COI committee have established a management plan that will be implemented for this project.

16 References

1. Park KH, Kim TW. OCT Imaging in Glaucoma : A Guide for Practitioners. Springer; 2021.
2. CDC. Don’t Let Glaucoma Steal Your Sight! Centers for Disease Control and Prevention. Published November 24, 2020. https://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html
3. Orbis International. Global blindness was slowing prior to pandemic study reveals. Orbis. Published October 11, 2021. https://www.orbis.org/en/news/2021/new-global-blindness-data

17 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

1. New Research Project Feasibility Questionnaire
2. Questionnaire for Subjects
3. Provisional Patent for the Novel Device
4. Recruitment telephone script

18 Schedule of Events

Activity	Study Visit
Study team procedures	
Consent subject	X
Select randomized imaging protocol	X
Clean first imaging device and attachments	X
Adjust chin rest / head mount	X
Image subject	X
First imaging session survey	X
Clean second imaging device and attachments	X
Adjust chin rest / head mount	X
Image subject	X
Second imaging session survey	X