INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Ngoc Nguyen, MD / Glaucoma Center of San Francisco / "The Effectiveness of DSLT in Asian Normal Tension Glaucoma Patients"**
Protocol Number:	**NTG_DSLT-001**
Principal Investigator: (Study Doctor)	**Ngoc Nguyen, MD and Shan Lin, MD**
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KEY INFORMATION

You are invited to take part in a research study. This research study is to evaluate the efficacy of the Direct Selective Laser Trabeculoplasty (DSLT) in Asian subjects with normal tension glaucoma (NTG). The device, BELKIN/ALCON Vision Eagle, is an FDA (United States Food and Drug Administration) approved device. However, how this device is used in this study is considered investigational. Please discuss with your study doctor if you have any questions or concerns.

Alcon is providing a research grant to conduct this research study. The Glaucoma Center of San Francisco is sponsoring this study.

- ***Main reason to join this study:*** *Be part of research to determine the clinical efficacy of the DSLT for normal tension glaucoma and possibly reduce the number of medications needed for your glaucoma.*
- ***Main reason not to join this study:*** *If you are unable to perform visual field testing or OCT testing, or are not able to have follow-ups with the study doctor for the next year, or do not want to receive DSLT study treatment, then this study may not be for you.*
- ***Research questions the study is trying to answer:*** *Does the DSLT reduce intraocular pressure (IOP) and medication use in Asian NTG subjects?*
- ***What information about you is being collected for the study:*** *Basic demographic information will be recorded such as your age, gender, and race/ethnicity. Standard-of-care eye procedures such as visual acuity, eye pressure, visual fields, OCT (optical*

coherence tomography) imaging test, and the number of medications you take will be recorded. Any complications or changes to your glaucoma treatment after the laser study treatment will also be recorded.

- ***What are the types of activities you will do in the research:*** *You will have routine follow-up visits with your eye surgeon and glaucoma testing such as optical coherence tomography (OCT) imaging and visual field test(s) after the laser study treatment.*
- ***In what ways is this research novel:*** *This is the first prospective study using DSLT in Asian populations with normal tension glaucoma (NTG) in the United States (U.S.).*

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have **normal tension glaucoma and are on 1-3 glaucoma medications.** Normal tension glaucoma is a type of glaucoma (an eye disease that damages the optic nerve) where vision loss happens **even though eye pressure is not high.**

The purpose of this research study is to evaluate the efficacy of the Direct Selective Laser Trabeculoplasty (DSLT) in Asian subjects with normal tension glaucoma (NTG).

The DSLT is an emerging variant of SLT that delivers laser energy without the need for a contact lens, thus making it a non-contact and potentially more patient-friendly procedure. However, the efficacy of the DSLT has not yet been reported in Asian NTG patients.

About 40 subjects (or 40 eyes, one eye for each subject) will be enrolled in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately one year after your eye surgery and will include approximately 7 visits (including pre-operative and post-operative standard visits) to your eye surgeon's clinic.

<u>Screening/Baseline Visit 1</u>:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Full ocular eye examination including gonioscopy, intraocular pressure measurement on medications, visual field test(s), and OCT imaging as standard of care.

- Study Washout Period: If you are on glaucoma medication(s), you will discontinue your glaucoma drops for 6 weeks. This is called a "washout period," during which the effects of these medications leave the eye.

- After 6 weeks, the IOP will be measured again. To qualify for the study and proceed to the procedure (study treatment), the IOP will need to be in a certain range (under 21mmHg).

Study Procedure (Visit 2):
You will receive a standard DSLT treatment; this involves using some eye drops including numbing medication. The medication will be removed post-procedure and your IOP will be checked at 5 minutes and 1-2 hours post-procedure for safety.

Visit 3: 1 month post-procedure (plus or minus 1 week)
- Return for follow-up eye exam and IOP check

Visits 4 and 5: 4 months and 8 months post-procedure (plus or minus 1 month)
- Return for follow-up eye exam and IOP check

Visit 6: 11 months post-procedure (plus or minus 1 month)
- Return for follow-up eye exam and IOP check
- If you are on glaucoma medication(s), you will do another washout period for 6 weeks.

Visit 7: 12-13 months post-procedure
- Return for follow-up and IOP check
- Repeat annual standard-of-care testing: HVF 24-2, OCT imaging, gonioscopy

After Study Treatment:
After the study treatment is over, you will continue routine care with your eye surgeon or the original referring provider for your glaucoma care.

EXPECTATIONS
If you participate in this study, you will be expected to:
- Follow up according to your eye surgeon's recommendations
- Be able to perform visual field and OCT imaging

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS
Risks of the DSLT:
In some cases, the eye laser procedure may not lower your eye pressure or control your glaucoma, even when it is properly performed. Your ophthalmologist cannot tell you about every risk. However, below are some of the most common and serious risks:

Common minor side effects:
- Discomfort and redness of eye, blurred vision, gritty sensation, pain
- Ocular inflammation

- Temporary IOP increase for hours or days after the procedure
- Corneal changes

Other Risks

There is no guarantee that the laser will improve your eye pressure. Further treatment such as glaucoma medication or surgery may be needed if there is glaucoma progression. Careful follow-up is required after laser. After the procedure, you will still need regular eye exams to monitor your glaucoma and watch for other eye problems.

RISKS OF STUDY PROCEDURES

- **Washout period** – The intraocular pressure will rise after the washout period. Therefore, it is important to return to your study site as instructed before the laser and after the laser to have your intraocular pressure checked. Your study doctor and/or eye surgeon will instruct you to resume the medication if the pressure exceeds the safety limit of the study. If you experience blurry vision and eye pain during the washout period, please contact your study doctor right away. In subjects with mild to moderate glaucoma, this short period of increased intraocular pressure typically will not cause any harm to your eyes.

There may be other study risks that are unknown.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your glaucoma. The alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you.

BENEFITS

You may benefit as a result of your participation in this study, including attentive care by the glaucoma specialist who performs your laser for the one-year span. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

You will be paid up to a total of **$400** if you complete this study in its entirety.

You will be paid for the visits you complete according to the following schedule:

- Baseline visit 1 $50
- Procedure visit 2 $50
- Visit 3, 4, 5 $50 each visit
- Visit 6 $75
- Visit 7 $75

You will be paid the amount after each visit. If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the study sponsor (namely its monitors and auditors),
- The institutional review board – Advarra IRB (an Institutional Review Board that reviewed the ethical aspects of this study to help protect the rights and welfare of study subjects),
- Government regulatory authorities including the US Food and Drug Administration (FDA) and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use, and disclosure of your information as described above.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result of the procedures done for the purpose of this study, your medical insurance should cover any expense since DSLT is an approved standard-of-care treatment.

Your study doctor and the sponsor of the study have no plans to provide compensation for any injury or harm resulting from the laser procedure performed by the eye surgeon, study doctor, and/or study staff. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS
There will be no additional charge for your DSLT study treatment or for your participation in this study. The study-related procedures and study visits will be covered by your insurance as standard of care.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00090893.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are

otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.
I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your regular doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the Glaucoma Center of San Francisco.
- The study doctor and study staff.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study treatment is helpful for Asian subjects with NTG.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received.

However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use, and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date