FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

59TH MEDICAL WING
INFORMED CONSENT DOCUMENT
[Adult, Child (14-17 years of age)]

Title of Protocol/Project:	Topography-guided vs. wavefront optimized corneal refractive surgery: A prospective contralateral randomized double-masked study
FWH #:	20200077H

This informed consent document (ICD) is written in second person for those individuals completing it for their own participation in the study. The language should be considered to refer to the research subject or when a parent/guardian or legally authorized representative (LAR) is completing the form on the research subject's behalf (example: a child). Therefore, this informed consent document will serve for an adult and a child (14-17 years of age) with a co-signature by a parent, legal guardian, LAR or surrogate/substitute consent. Children 7-13 years of age must sign an Assent Form.

KEY INFORMATION ABOUT STUDY PARTICIPATION:
Study Summary: Many different lasers and treatment programs are available to perform LASIK and PRK (laser refractive eye surgery). New programs or "algorithms" occasionally emerge and several different treatment options are used in our center. A laser algorithm is the pattern of laser used to change the shape of the cornea. We are seeking to test two such algorithms. We use them both and both are standard of care. One is very labor and resource intensive. As a participant in this study, you will undergo the exact same pre-operative evaluation and receive the same pre and post-operative care as if you were not part of the study. If eligible and after a determination is made for either LASIK or PRK, one of your eyes will be treated with one algorithm (Contoura Vision) and the other eye with the other algorithm (Wave-Front Optimized). You will not know which eye received which treatment algorithm. You will be required to be present for all pre-operative assessments and post-operative visits on day 1, week 1, month 1, month 3 and month 6.

As stated above, you will be expected to be present for post-operative visits up to 6 months after surgery. You will have no additional risks than would be expected for a person undergoing laser refractive surgery who is not part of this study (in addition to this consent form, you will be required to sign a surgical consent form that will discuss the risks/benefits of the refractive surgery procedure you will undergo). You will incur no financial risks and you will receive no financial benefit from this study.

Participation in this study is voluntary so you may choose to not be a participant in the study and still receive refractive surgery. If you choose not to participate in this study, do not complete this form. As an alternative to this study, if other studies are available, you may choose to participate in those studies.

INFORMATION ABOUT THIS CONSENT FORM:
You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed.

Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to your friends, family, or a doctor about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the purpose and procedures of the study, including risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION:
Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before the study is completed, your decision will not affect your eligibility for care or any other benefits to which you are entitled as a DoD beneficiary. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR:
The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Charisma B. Evangelista, MD	Maj	USAF	Ophthalmology, WHASC

PURPOSE OF THIS STUDY (Why is this study being done?)**:**
You are being asked to consider participation in a research study that will be comparing two different types of laser refractive surgery treatment options. You will undergo either LASIK or PRK, however each eye will receive one of two different laser treatment algorithms (Contoura Vision or Wave-Front Optimized).

The purpose of this study is to show whether one of these laser treatment algorithms is superior to the other. Currently, both are standard of care and both are used at this facility.

You have been selected to participate in this study because you are considering refractive surgery.

This study will enroll approximately 400 subjects overall with approximately 200 subjects to be enrolled at the

Joint Warfighter Refractive Surgery Center, JBSA Lackland, TX, and 200 subjects to be enrolled at the Refractive Surgery Center located at Joint Base Elmendorf-Richardson, AK, over the next twenty-four months.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, a publicly available Federal website, 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. Additionally, an IRB-approved copy of the clinical trial template consent form will be posted with no subject information included on the form. You can search this website at any time.

PROCEDURES:

If you decide to take part in this research study, you will be asked to sign this consent form.

During your participation in this study, you will be asked to make approximately seven visits with Dr. Charisma Evangelista, the Principal Investigator (PI), or his study staff. It may be necessary for you to return to the Warfighter Refractive Surgery Center at regularly planned intervals, to include post-operative day 1, week 1, month 1, month 3 and month 6.

As a research participant, you will undergo the following research-related procedures: either LAISK or PRK with one eye randomized to undergo Contoura Vision treatment and the other eye to undergo Wave-Front Optimized.

SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY:
No study specific screening will be required for you to participate in this study. As a participant in the study, you will undergo the normal screening and standard of care procedures for either LASIK or PRK.

Assignment to Research-Related Study Groups:
When it is determined that you are eligible for the study and after you and your surgeon choose the surgical procedure that is best for you (LASIK or PRK), you will be assigned by chance (like flipping a coin) to have one eye treated with the Contoura Vision treatment algorithm and the other by Wave-Front Optimized. You will not know which eye is receiving which treatment. The researchers will know which treatment is assigned to which eye. However, the technicians performing the post-operative screenings/evaluations will not know which eye had which treatment.

Study Procedures/Background
Background: Many different lasers and treatment algorithms are available to perform LASIK and PRK (laser refractive eye surgery). New algorithms occasionally emerge and several different treatment options are used in our center. We are seeking to test two such algorithms. We use them both currently and both are standard of care. One, however, is very labor and resource intensive. As a participant in this study, you will undergo the exact same pre-operative evaluation and receive the same pre and postoperative care as if you were not part of the study. If eligible and after a determination is made for either LASIK or PRK, one of your eyes will be

treated with one algorithm (Contoura Vision) and the other eye with the other algorithm (Wave-Front Optimized). You will not know which eye received which treatment algorithm. You will be required to be present for all pre-operative assessments and post-operative visits on day 1, week 1, month 1, month 3 and month 6. Pre-operative visits may take up to 6 hours, including measurements and discussions of treatment options with your surgeon. Post-operative visits are typically quicker. If dilated, these visits take longer. Most post-operative visits take between 30 minutes and 3 hours. As with all LASIK/PRK patients, your pre-operative planning will consist of a brief that teaches about the differences between LASIK and PRK. Occasionally, your pre-operative data/screening will preclude you from one or both laser treatments (LASIK and PRK). If you are not eligible for one, you will be told. If you are not eligible for either, you will not be allowed to participate in the study. If you are eligible for both, you and your surgeon will discuss the options and decide together which is best for you. You will have no say in which eye undergoes Contoura Vision or Wave-Front Optimized. Laser eye surgery can be painful, however we will do our best to minimize your discomfort. No additional pain will be experienced as part of this study that you would not endure if undergoing laser refractive

surgery not as a study participant. This will be explained to you more in your pre-operative brief. No investigational drugs or devices will be used.

Participation in this study is voluntary. As stated above, you will be expected to be present for outpatient post-operative visits up to 6 months after surgery. You will have no additional risks than would be expected from a person undergoing laser refractive surgery who is not part of this study. You will incur no financial risks and you will receive no financial benefit from this study. You may choose to not be a participant in the study. If other studies are available, you may choose to participate in those studies.

RISKS OR DISCOMFORTS:
There iare no known risk associated with this study. However, you may experience some normal eye discomfort or irritation associated with your surgery. You will be required to review and sign a separate consent form that will discuss the risks and any discomfort associated with the surgical procedure you will undergo. Your surgeon will also discuss this with you and answer any questions you may have prior to your surgery.

ARE THERE RISKS IF YOU ALSO PARTICIPATE IN OTHER RESEARCH STUDIES?
Being in more than one research study at the same time, *[or even at different times,]* may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

There may also be unforeseen risks associated with this or any research study.

WITHDRAWAL FROM THE STUDY:
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and
you will not be penalized or lose any benefits to which you would otherwise be entitled as a DoD beneficiary.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

COULD YOUR PARTICIPATION END EARLY?
The researcher may withdraw you from the study prior to the study's end without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.
- The researcher decides that continuing your participation is not in your best interests.
- You become ineligible to participate.
- You need treatment not allowed in the study.
- The study is cancelled.
- Unanticipated circumstances.

If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

BENEFITS:
There is no guarantee or promise that you will receive any personal benefit from this study. We hope the information learned from this study may help future patients. Currently, both laser algorithms are being used in the DoD. Newer does not always mean better and there is a significant increase in time to prepare for one of the algorithms versus the other. If this study can prove there is no difference, we can better justify why the additional pre-operative testing is not necessary. This could greatly reduce the burden on our ophthalmic technicians and physicans as well as benefit future patients in shorter presurgical testing.

COSTS: Will taking part in this study cost anything?
The investigators have designed this study so that there is no cost to you to participate in this study other than what it will cost you to travel to the research appointments, beyond any scheduled standard of care appointments.

The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by Federal laws and regulations.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS:
Alternatives to receiving the refractive surgery procedures that are being offered to the study participants may be available to you. For example, you may be eligible for SMILE refractive surgery that is not available to study participants. You also may receive the same refractive surgery procedure as offered to subjects in this study as a non-study patient. Choosing not to participate in this study is always an alternative as well.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, *Privacy Act Statement- Military Health Records*, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the Air Force, the DoD, other government agencies that oversee human research, and the San Antonio Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Information collected on this study about you that represents standard care

and results of tests run by accredited laboratories will be placed in your medical record. Your medical record will be annotated to reflect you are participating in a research study for each visit because this study involves an intervention that is for research purposes only. All information about you collected on this study will be kept in an electronic database, which will be double password-protected, firewall protected and access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to
assist you in contacting the 59 MDW Privacy Office for assistance.

ENTITLEMENT TO CARE:
If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may also contact the 59 Authorized Institutional Official (AIO) at 210-292-3355.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

BLOOD, TISSUE & BIOLOGICAL SAMPLES:
No specimens or samples will be collected.

CONTACT INFORMATION:
****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI):
The principal investigator and an alternate member of the research staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Maj Charisma B. Evangelista, MD Duty and After-Hours Phone: 210-292-4233

Alternate Contact:

Associate Investigator: MAJ Gary Legault, MD Duty and After-Hours Phone: 210-266-1458

Institutional Review Board (IRB):

If you have any questions about your rights as a research participant, or if you have concerns or complaints about the research study, please contact the IRB Office at:

Mailing Address:
San Antonio IRB Office, Brooke Army Medical Center
ATTN: MCHE-ZQ, Department of Quality and Safety
3551 Roger Brooke Drive
Fort Sam Houston, Texas 78234-4504
Phone: 210-916-2598

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form will be given to you for your records.

_____ _____
VOLUNTEER'S SIGNATURE **DATE**

_____
PRINTED NAME OF VOLUNTEER

_____ _____
ADVISING INVESTIGATOR'S SIGNATURE **DATE**

_____
PRINTED NAME OF ADVISING INVESTIGATOR

Office of Clinical Research Support Use Only:
FWH20200077H, Evangelista, ICD, PR 2022