APPROVED BY SALUS IRB: 23 JUNE 2023

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor: Lightfield Medical
City and State: Minneapolis, MN

Protocol Number and Title: Protocol 001, Feasibility Study of a Novel Automated Slit Lamp Camera (Lightfield Medical Ophthalmic Camera Model Vscan001)

Study Doctor: John Stephen Berestka, MD

Address of Study Site(s): Northwest Eye
8501 Golden Valley Road
Golden Valley, MN 55427

24-Hour Telephone Number: 763-438-8697/763-416-7600

INTRODUCTION

You are being invited to take part in a medical research study. Before you decide to take part in this study, you should read this document. This document, called an informed consent document, explains the study. Please ask as many questions as needed so that you can decide if you want to be in the study.

To be in this research study, you cannot already be in another medical research study or have been in another study within 30 days prior to screening for this study.

You must be honest and complete in providing your medical history.

PURPOSE OF THE STUDY

The study sponsor has designed a new automated camera that can take high speed pictures of the front of the eye. Sitting for the eye photos is similar to having your eye examined at an eye appointment. You will place your head on a chin and forehead rest. A light will shine on your eye from different angles. Pictures of the eye will be taken from each position.

Automatic photography of the eye might help doctors document the eye exam. Automated photography might also allow doctors to review exams done in remote locations.

The device is considered investigational. "Investigational" means that the device being tested has not been approved by the United States Food and Drug Administration (FDA) for prescription or over-the-counter use.

WHAT WILL HAPPEN DURING THE STUDY

You will answer some brief questions about your medical history. We will screen you to make sure you can physically place your head on the chin and forehead rest and hold still. If you cannot position your head and hold still, you will not be invited to take part in the study.

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LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS EXPECTED TO TAKE PART

The study will take approximately 15-30 minutes. The photography part of the study will take 3-10 minutes. Only one visit is required. Some patients may be invited to come back for additional photography if they have an eye condition that changes over time. Between 50 and 200 adults over 18 years of age are expected to be in the study.

SIDE EFFECTS AND OTHER RISKS

Because this is the first time this device is being used to photograph people, all of its side effects are not known.

One of the reasons for this study is to learn more about the possible side effects of the device. It is important that you tell the study staff about possible side effects.

The most common side effects of the study device include: temporary light sensitivity and an after image.

The least common side effects of the study device include: soft tissue injury to your nose, chin or forehead if they come into contact with the device. The device has been tested and found to produce a safe amount of light according to recognized standards, but light damage to your eye could be possible.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

UNFORESEEABLE RISKS

The use of this study device may involve risks to you that are presently unforeseen and unknown.

Because this device is investigational, all of its side effects may not be known. There may be rare or unknown side effects that could possibly occur, including life-threatening reactions.

POSSIBLE BENEFITS OF THE STUDY

Since this study does not provide a medical treatment, there is no direct benefit to you. Information learned from the study may help other people in the future.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

EMPLOYEES OR FAMILY MEMBERS OF THE STUDY DOCTOR, STUDY STAFF OR SPONSOR

If you are an employee or family member of the study doctor, study staff, or sponsor, the following statements apply:

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- Your decision to participate or not, will not affect your or your family member's performance evaluations
- Your decision to participate or not, will not affect your or your family member's opportunity for promotion
- Your decision to participate or not, will not affect your or your family member's pay

ALTERNATIVES TO PARTICIPATION

You are not receiving the study device as a treatment for a medical condition. Therefore, your only other choice is not to take part in this research study.

RELEASE OF MEDICAL RECORDS AND PRIVACY

Your study records will be kept private. There may be times when the study doctor will not be able to guarantee privacy, such as when your study medical records are requested by a court of law or when shared with a firm in another country that does not have privacy regulations in place. Salus Independent Review Board and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If information from this study is published or presented at scientific or innovation meetings, your name and other personal information will not be used. The following people will have access to your study records:

- Study Doctor
- Study Monitor or Auditor
- Sponsor Company or Research Institution
- Salus Independent Review Board
- The United States Food and Drug Administration (FDA)
- Other State or Federal Regulatory Agencies

Salus Independent Review Board has approved this study and this informed consent document. Salus IRB is a committee of scientific and non-scientific individuals who review, require modifications to, and approve or disapprove research studies by following the federal laws. This group is also required by the federal regulations to provide periodic review of ongoing research studies.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call them at the number listed on the first page of this consent document.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

CONFLICTS OF INTEREST

The study doctor is being paid to conduct this study. It is also important for you to be aware that the principal investigator of this study, John S. Berestka MD, has a conflict of interest related to the medical device being studied. He is the inventor of the device and holds patents covering its intellectual property. Additionally, he is a

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shareholder in the company responsible for manufacturing the device. His son, Matthew Berestka, is also on the study research staff. Matthew Berestka is a co-inventor of the device and indirectly has a financial interest in the company responsible for manufacturing the device.

To ensure transparency and unbiased evaluation, steps have been taken to mitigate the potential influence of this conflict of interest. Independent oversight and monitoring bodies, such as the independent review board (IRB) and regulatory authorities, will review the study protocol and monitor its progress. The study will be conducted in accordance with applicable laws, regulations, and ethical guidelines.

LEGAL RIGHTS

You do not lose any legal rights by signing this consent document. The above statement, "In Case of an Injury Related to This Research Study," does not stop you from seeking legal help in case of negligence.

NEW FINDINGS

During the study, you will be told of any important new findings about the study device. You can then decide if you still want to be in the study.

WHOM TO CONTACT

You may contact the study doctor or study staff at the phone number listed on the first page of this consent document:

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you need medical attention please go to the nearest emergency room.

You may contact Salus Independent Review Board if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

LEAVING THE STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. You have the right to leave this study at any time. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

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If you wish to leave this study, please call the study doctor or study staff at the telephone number listed on the first page of this consent document to schedule study exit procedures.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Study Doctor
- Sponsor Company
- Salus IRB
- The United States Food and Drug Administration (FDA)
- Other State and Federal Regulatory Agencies

If you do not follow the study procedures you may be taken out of the study.

If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study sponsor.

FUTURE RESEARCH

Your personal information (identifiers) might be removed from the photographs obtained and after such removal, the photographs could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

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AGREEMENT TO BE IN THE STUDY

This consent document contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent document, please ask the person explaining this document or one of the study staff.

By consenting to participate you agree that you have been given a copy of all pages of this consent document. You have had an opportunity to ask questions and received satisfactory answers to all your questions about this study. You understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care. You understand that your study-related medical records may be reviewed by the company sponsoring the study and by government authorities.

You will be given a signed and dated copy of this informed consent document to keep.

**IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE,
YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.**

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Informed Consent Document

_____ _____
Signature of Person Explaining Informed Consent Document Date

Addendum for Study Personnel who are employees or are participating as subjects in the calibration phase of the study

For subjects who are employees of Northwest Eye Clinic/Unifeye Vision Partners, you should know that the principal investigator of the study, John S. Berestka, MD, has a small (less than 2%) equity ownership of Northwest Eye Clinic.

Your participation in the study is voluntary and will in no way affect your current employment with Northwest Eye Clinic/Unifeye Vision Partners.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

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For subjects who are also participating as study personnel—and/or related to the principal investigator for this study:

Your participation in the study is voluntary. You may decline to participate as a subject and continue on in your role as study personnel without any consequences.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

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