IRB Approved: 2/23/2026
Approval Expires: 7/10/2026

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: ___ 28798_____

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Evaluation of a new retinal imaging camera: the iCam OCT (inpatient)

PRINCIPAL INVESTIGATOR: J. Peter Campbell, M.D., MPH 503-494-7891

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE:
The objective of this study is to collect retinal images with a new retinal imaging prototype device to develop and evaluate its performance and clinical utility. The iCam OCT will be referred to as the study device throughout this form. This device is not approved by the Food and Drug Administration (FDA).

Please take your time and read this document carefully before deciding. You should not join this research study until all of your questions have been answered to your satisfaction.

DURATION:
Your participation in the study will consist of imaging along with the standard scheduled eye exam for as long as you are in the hospital. The study portion of the visit will last up to 5 minutes. Your participation in this research is completely voluntary. You can choose not to participate. If you decide to participate, you can change your mind and stop participating at any time, for any reason.

PROCEDURES:
If you decide to take part in this study, you will have imaging performed on both eyes using the study device for 1 or more visits. Imaging with the study device will be performed with dilation of the pupil. Lubricating drops may be used as needed. Imaging sessions will not last longer than 5 minutes and will be in addition to your routine eye exam.

This study does not include genetic testing.

RISKS: The risks of study participation are relatively low, and we believe that they do not constitute more than minimal risk. For any eye exam, there is risk of pauses in breathing and

lower than normal heart rate, especially in the instance of examining premature infants who are often unstable medically. When imaging with the device, there are low risks of scratches on the outer surface of the eye or infection.

BENEFITS: You will not directly benefit from taking part in this research. However, by being a participant, you may help us learn how to help patients in the future.

ALTERNATIVES:
This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

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Research Consent and Authorization Form

TITLE: Evaluation of a new retinal imaging camera: the iCam OCT (inpatient)

PRINCIPAL INVESTIGATOR:	J. Peter Campbell, MD, MPH	(503)494-7891
CO-INVESTIGATORS:	Benjamin K. Young, MD	(503)494-7891
	Yifan Jian, PhD	(503)494-6431

WHO IS PAYING FOR THE STUDY?:
M.J. Murdock Charitable Trust
Siloam Vision
U.S. Department of Defense

WHO IS PROVIDING SUPPORT FOR THE STUDY?: Siloam Vision is owner of the study device (iCam OCT) and is providing the device to OHSU to conduct the research. OHSU is being compensated by the funder to conduct this study. This is to pay for tests performed only for study purposes and for the time involved on the part of the study doctor(s) and research staff. You may freely discuss this with your medical provider and the study doctor if you have concerns.

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?: OHSU and Drs. Campbell, Jian and Coyner have a financial interest in Siloam Vision, a company that is developing the technology used in this research study. The nature of this financial interest and the design of the study have been reviewed by two committees at OHSU. They have put in place a plan to help ensure that this research study is not affected by the financial interest. If you would like more information, please contact the OHSU Research Integrity Office at coir@ohsu.edu.

WHY IS THIS STUDY BEING DONE?:
"You" means you or your child in this consent form. You have been invited to be in this research study because you are at risk of Retinopathy of Prematurity (ROP), a potentially blinding disease, and are scheduled for routine screening for this disease while inpatient at OHSU Doernbecher Neonatal Intensive Care Unit (NICU).

The purpose of this study is to look at optical coherence tomography (OCT) scans from the study device, which are a different way to take pictures of your eye. The researchers want to see if OCT scans are better than or the same as the standard retinopathy of prematurity (ROP) exam that is usually performed for diagnosing or monitoring ROP.

The use of the unapproved device for eye conditions is experimental. The study device has not been approved by the FDA because we do not know enough about it.

If you are an inpatient requiring ROP screening, you may have images taken during the routine ROP examination at the discretion of the attending ophthalmologist (Drs. Campbell or Young). At least one imaging session obtained by the study device will be compared with the standard ROP exam. Imaging may be obtained with the study device during routine ROP screening until you are discharged from the NICU.

We are asking you to provide retinal images for an image bank, also called a repository. These samples will be stored indefinitely and may be used and disclosed in the future for research.

Up 500 patients will be enrolled in this study at OHSU.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

Once enrolled, patients will be imaged with the study device. For inpatient subjects requiring ROP screening in the NICU, an eye doctor will perform a routine eye exam using a device called an ophthalmoscope. The eye doctor shines a bright headlamp on the ophthalmoscope into your eye while holding a magnifying lens to get a detailed, broad view of the back of the eye in order to evaluate the presence and/or extent of the ROP eye disease. This is standard care and will be performed even if you are not in the study. If you agree to be in this study, you will also have OCT images obtained by the study device. One or both eyes may be imaged to compare with the standard eye examination. This involves placing artificial tears gel (also known as lubricating gel) on the eye to help protect from scratches as well as to help fill the space between the camera lens and the eye, eliminating air bubbles that can distort the image and blur the view of the back of the eye. The photographer then uses the handheld device to touch the lens to the eye and capture images of the back of the eye for disease evaluation. We will take OCT images at least one time. We may take more images while you are in the hospital until you are discharged.

Lubricating drops may be reapplied as needed.

All images captured will be recorded on a study form along with other basic information. This additional information will be collected from your medical record and will include date of birth, gender, birthweight and gestational age, race and ethnicity (optional), as well as history of eye issues.

Imaging from the study device will be performed at least 1 time and will take up to 5 minutes. The entire visit including routine care and routine imaging will take approximately 60 minutes.

In the future, your images may be given to researchers for other research studies. The images will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WILL I RECEIVE RESULTS FROM THE TESTING IN THIS STUDY?

Research results will not be shared. Only standard clinical results will be placed in your medical record.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
The risks of study participation are relatively low, and we believe that they do not constitute more than minimal risk. For inpatient infants, we believe that the risks of imaging using the contact version of the device are equal to that of the standard eye exam which include low risks of scratches on the outer surface of the eye or infection. There is less discomfort from the contact device compared to the standard eye exam from the light being used because of the invisible light used in the study device. For any eye exam, including the imaging with the non-contact or contact device there is also risk of pauses in breathing and lower than normal heart rate especially in the instance of examining premature infants who are often unstable medically. Published studies have shown that photography appears less stressful to infants than standard clinical examinations. The investigators believe this does not present more risk than what there would normally be for a routine eye exam. Premature infants will be watched closely by the neonatalogy staff to make sure they are medically stable for participation in this study. (This is routinely done by neonatologists in assessing whether infants are stable for routine ROP examinations.)

You may choose not to be in this study.

WHO WILL SEE MY PERSONAL INFORMATION?:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository for future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, Siloam Vision and the Department of Defense and the funder's representatives
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

Images from this study may be shared with other investigators for future research studies. All identifying information about you will be removed from the data before they are released to any other investigators.

We may continue to use and disclose your information as described above indefinitely

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT? Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?: There will be no cost to you or your insurance company to participate in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Pete Campbell at 503-494-7891.

If you are injured or harmed by the study procedures or study device, you will be treated. OHSU and the funders do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon Law (Oregon Tort claims act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on the subject, please call the OHSU research integrity office at (503)494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in the study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Pete Campbell (503) 494-7891.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research participant in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

J. Peter Campbell, MD
515 SW Campus Drive
Portland, OR 97239

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The images we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name (or parent/guardian if subject is under 18)	Subject Signature (or parent/guardian if subject is under 18)	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____

(state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.