INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF STUDY:	Comparative Study of the OCT-HS100 with OCT Angiography and the RTVue XR OCT with Avanti with AngioVue Software
NAME OF SPONSOR COMPANY:	Canon, Inc.
PROTOCOL NUMBER OF STUDY:	CANON-OCT-US-001
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR):	David Lally, MD
ADDRESS OF STUDY SITE(S):	New England Retina Consultants 3640 Main Street, Suite, 201, 304 Springfield, MA 0118
TELEPHONE NUMBER (DAYTIME):	(413)732-2333
AFTER HOURS TELEPHONE:	(413)732-2333

WHY AM I BEING ASKED TO VOLUNTEER?
You are being invited to take part in a research study. You have been asked to be in this study because you are at least 18 years of age and you are able to follow instructions from the study doctor/staff. Your participation in the study is voluntary, which means that you can choose to participate or not.

Before you agree to participate in this study, it is important that you read this consent form and are aware of both the study purpose and procedures. Your study doctor will talk to you about the research study and will give you this consent form to read. You may also talk to family, friends, and your personal physician about your decision. If you find some of the medical language difficult to understand, please ask your study doctor any questions you have about the study. If you have more questions later, Dr. David Lally will be happy to answer them for you.

If you decide to take part in this study, you will be asked to sign and date this form. You will receive a copy of the signed and dated form to take home.

The Sponsor of this study is Canon, Inc. The Sponsor is paying the study doctor and study staff for their work on this research study.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

Researchers have developed a new investigational device. "Investigational" means that it has not been approved by United States Food and Drug Administration (FDA). The device is called the Canon HS100 OCT. OCT stands for Optical Coherence Tomography, which is technology that uses light to take pictures of the inside of the eye. The device takes pictures of the inside of the eye without touching the eye.

The purpose of this study is to determine whether the investigational device is as safe and effective as a similar, FDA-approved device. The pictures taken of the inside of the eye using the Canon HS100 OCT will be compared to the pictures taken of the inside of the eye using an FDA-approved device called the Optovue RTVue XR.

This study will also determine whether there are any safety issues with the investigational device.

STUDY PROCEDURES/SAFETY ASSESSMENTS
At times specified in this consent form, you will be asked to read an eye chart and have your eyes examined by the study doctor. The study doctor may also test for any sight threatening adverse events (unfavorable side effects) associated with any of the devices being used in this study.

HOW LONG WILL THE STUDY LAST? HOW MANY PEOPLE WILL BE IN THE STUDY?
This study consists of one (1) study visit that may last up to four (4) hours. You may be asked to return for a second study visit if you do not finish all of the study procedures during the first visit. Up to 236 people at one (1) site will be enrolled. Study participants will be male and female, at least 18 years of age and of any race. Data will be collected from one eye for all study participants. All of the data collected will be included in data analysis. The goal is to obtain evaluable data from at least 99 eyes.

WHAT WILL HAPPEN DURING THE STUDY?
Office Visit Lasting for up to 4 hours:
You will be asked to read and sign this consent form before you begin the study. Then, some questions will be asked and some routine exams will be done to make sure you can be in this study:

- Demographics: You will be asked questions about your age, race, gender, etc.;
- Ophthalmic Medical History: You will be asked questions about your eye medical history;
- Visual Acuity: You will read different sized letters on an eye chart to check your vision. A second visual acuity may be done at the end of the visit if the doctor thinks you need it;
- Slit Lamp Exam: You will be given an eye examination by a study doctor to check the health of your eyes. The study doctor will use an instrument to shine a thin beam of light into the eye to see the different parts of your eye. The study doctor will also evaluate your eyelids;
- Intraocular Pressure: You will have numbing eye drops and orange/yellow dye put into your eyes. The study doctor will measure your eye pressure by touching each of your eyes briefly

- Fundus Exam: The study doctor will look into your eyes with a light to assess the health of the back of your eyes. No eye drops will be used for this examination. Your eyes will not be dilated for this exam.
- Humphrey Field Analyzer (HFA): Measured on the day of the study visit or within the previous two (2) months from the study. A study staff member will complete this visual field testing if you are part of the glaucoma group and have not had this completed already within two (2) months of your visit 1.
- Fundus Fluorescein Angiography (FFA) (only 12 patients will be asked to undergo this assessment): Fluorescein angiography may result in bleeding and bruising around the needle stick and/or itching, rash or vomiting. Mild reactions such as itching, swelling, or redness near where the dye is put in your vein are more common. These have been estimated to happen about 1 out of 100 times. Rarely, severe allergic reactions can also happen during this test. Serious allergic reactions such as severe swelling and difficulty breathing can happen in 1 out of 10,000 subjects. About 1 out of 222,000 people can have a heart attack, stroke (blood clots in the brain), or even die from the fluorescein dye administration.

If you are eligible to continue based on the questions and tests described above, you will have pictures of your eyes taken using the two (2) study devices. You will have the following measurements taken on both of your eyes:

- Canon HS100 OCT: Pictures will be taken of the inside of your eye using light. You will be asked to sit in front of the device with your head positioned between chin and forehead rests. You will be asked to keep your eyes open and look straight ahead while pictures are taken of the inside of your eye. The device will not touch your eye.
- Optovue RTVue XR: Pictures will be taken of the inside of your eye using light. You will be asked to sit in front of the device with your head positioned between chin and forehead rests. You will be asked to keep your eyes open and look straight ahead while pictures are taken of the inside of your eye. The device will not touch your eye.

The order that you will have pictures taken on each device will be random, like the flip of a coin. You may be asked to read an eye chart and have your eyes examined by the study doctor after all pictures are taken.

WHAT ARE MY RESPONSIBILITIES?
If you are chosen to participate in this study, you are required to follow study instructions given by the study staff. It is important that you tell the truth about your medical history. It is also important that you tell the study staff and/or study doctor about any problems you have during the study.

If you decide to leave the study, you must contact the study doctor. You may be asked to return for a final visit to make sure that you are in your usual state of health.

THE RISKS OF MY PARTICIPATION IN THE STUDY
You might feel tired from the eye exams or study procedures. Also, the eye exams and measurements may pose risks because some devices come very close to or touch your eyes.

There is a small chance that the instrument used could scratch the surface of your eye. If that occurs, it is usually minor. Also, you may experience blurred vision or discomfort from the numbing drop that the study doctor gives you. These could last up to 24 hours after the exam. Also, there is a risk of allergic reaction (itching, redness, burning, or mucous discharge) to the ingredients in the anesthetic (numbing) eye drop used in these evaluations. If experienced, this could last up to 12 hours. Because your eyes are numb, it's important that you do not rub your eyes for at least 20 minutes after the exam.

The orange-yellow (Fluorescein) dye that will be put in your eyes to evaluate the intraocular pressure (pressure inside your eye) may make your skin and bodily secretions and excretions, such as your tears or mucous, change color, or they may cause some irritation to your eyes. This effect is usually temporary and disappears within a day. Rarely, people can have an allergic reaction to fluorescein dye. This would usually involve itching, swelling, or redness. If you develop such a reaction, you will receive treatment. As with any allergy, more serious or life threatening reactions are possible.

No adverse reactions (bad side effects) have been reported for the Canon HS100 OCT or Optovue RTVue XR devices.

Because the Canon HS100 OCT device is investigational (not yet FDA-approved), all of its side effects may not be known. There may be rare and unknown side effects. You must tell the study doctor and staff if you experience any side effects. If you are not honest about your side effects, it may not be safe for you to be in the study.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY?
During the study, we may learn new information about the device that could be important to you. This includes information that might cause you to change your mind about being in the study. You may be asked to sign a new consent form if this occurs. The study doctor will let you know as soon as possible if such information becomes available.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?
There is no direct medical benefit to you for participating in this study, except you may gain information about your ocular (eye) health. Also, this research may help others if the device is found to be safe and effective.

WHAT OTHER CHOICES DO I HAVE IF I DECIDE NOT TO PARTICIPATE?
This study is for research purposes only. The only other choice would be to not participate in the study.

WILL I BE PAID FOR BEING IN THE STUDY?
You will be paid $150 if you complete the study visit. If you screen fail (do not qualify to continue with the study), you will be paid $150. Study payment will be in the form of a check and sent to you within four (4) weeks after you have completed the study visit.

WILL I HAVE TO PAY FOR ANYTHING DURING THE STUDY?

There is no cost to you to take part in this research study. Procedures that are done only for the study, such as eye exams, will not be billed to you or your insurance company.

WHAT HAPPENS IF I AM INJURED OR HURT DURING THE STUDY?
If you become ill or get hurt during the study, get the proper medical care right away. If your illness or injury is a direct result of your study participation, medical treatment will be provided to you at no cost through the study doctor. However, financial compensation is not routinely available from the study site or the Sponsor for things such as lost wages, disability, or discomfort. If your illness or injury is not a direct result of your study participation, you and/or your insurance will be billed for the cost of the medical care of that illness or injury. If you have any questions about getting medical care and/or compensation, please ask your study doctor.

You still have the right to make a claim through the legal system even if you sign this form, accept medical care, and/or accept payment for medical expenses.

If you become ill or get hurt during the study, please contact the study doctor.

WHAT IF I DECIDE NOT TO TAKE PART IN THE STUDY OR WANT TO LEAVE THE STUDY EARLY?
Taking part in the study is your choice (voluntary). There is no penalty if you decide not to participate in the study. If you decide not to be in the study, you will not lose any benefits you would otherwise receive. You may leave the study at any time without penalty. If you choose to leave the study, your decision will not affect your ongoing or future medical care in any way. If you decide to leave the study or are taken out of the study, you may be asked to return for a final visit to make sure that you are in good health.

WHAT IF THE SPONSOR OR STUDY DOCTOR DECIDES TO STOP THE STUDY?
The Sponsor or study doctor can decide to stop the study at any time. Your participation in this study may be stopped if you do not follow the study doctor or staff's instructions or if your study doctor feels that it is necessary for your health or safety. You may be asked to leave the study even if you do not want to leave. If you decide to leave the study or are taken out of the study, you may be asked to return for a final visit to make sure that you are in good health.

If you leave the study, data (information) collected on you to the point of withdrawal remains part of the study database and may not be removed.

The study doctor, the Sponsor or its representatives, Alpha Independent Review Board, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study doctor's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

WHO CAN SEE OR USE MY PERSONAL INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Information obtained about you for this study will be kept private to the extent allowed by law. Your personal health information may be shared with certain people from certain organizations, known as "authorized users," who need to see, copy, and/or use this information in order to do their part in the study. The authorized users will receive full access to your original personal health information, which may or may not include your name. It is possible that your personal health information can be traced back to you even if it does not include your name. Therefore, complete privacy of your health information may not be possible. By signing this consent form, you are giving your study doctor permission to share your personal health information with all authorized users.

Authorized users may include, but are not limited to:
Representatives of Canon, Inc.
Representatives of Ora, Inc.
Representatives of New England Retina Consultants
The Food and Drug Administration (FDA) and other US governmental agencies
Alpha Independent Review Board (Alpha IRB)

Information obtained from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

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.
For safety reasons, your primary health care provider should know that you are taking part in this study. However, your study doctor will need permission from you before he can notify your primary health care provider. You will be asked to complete the Primary Care Physician/Specialist Notification option form below that will allow your study doctor to notify your primary health care provider.

PRIMARY CARE PHYSICIAN/SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in the study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist.

If you have any questions about this study, or the research, please contact the study doctor.

WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THE STUDY AND MY RIGHTS AS A RESEARCH SUBJECT?

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Alpha IRB, Attn: Marianne Thornton, toll free at (888) 265-5766 between the hours of 8:00am-5:00pm Pacific Time.

Alpha Independent Review Board
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
(888) 265-5766 (toll free)

Alpha IRB is a group of people who perform independent review of research studies to protect the rights and welfare of study participants. Although Alpha IRB has approved the information provided in this informed consent form and has approved for the study doctor to do the study, this does not mean Alpha IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

STATEMENT OF CONSENT

I have read this form and its contents were discussed with me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a copy of this signed and dated consent form for my records. I am not giving up any of my legal rights by signing this form.

_____
Printed Name of Subject

_____ _____/_____/_____
Signature of Subject Date

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully discussed the nature and purpose of the above study with the subject. The subject has had time to review this form and had an opportunity to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____
Printed Name of Person Conducting Consent

_____ _____/_____/_____
Signature of Person Conducting Consent Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on the study documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present, and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your personal doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct the study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

Canon, Inc. – The sponsor of this study and anyone working on behalf of the Sponsor to conduct this study (referred to as "the Sponsor"). The Sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures, and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the Sponsor. The Sponsor may, however, look at your complete study records that identify you. In addition, the Sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.

Ora, Inc. – the staff conducting the research with your study doctor.

Alpha Independent Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Independent Review Board.

The study doctor or Sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some, or all, of your PHI until the Sponsor has completed all work related to this study. At that time, you may ask to see your records.

This authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue in this study.

You will receive a copy of this Authorization after you have signed it.

_____
Printed Name of Subject

_____ _____/_____/_____
Signature of Subject Date

_____
Printed Name of the Person Obtaining the Authorization

_____ _____/_____/_____
Signature of Person Obtaining the Authorization Date