DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

Concise Summary

The purpose of this research study is to better understand the impact of visual impairment caused by different eye diseases in the ability to perform daily activities.

Participants will undergo standard eye examination, measurement of intraocular pressure, blood pressure, heart rate, height and weight, retinal metabolism, visual function and visual performance tests, brain wave test, virtual reality tests, balance assessment, driving simulation, and completion of questionnaires. All tests are non-invasive. If you are asked to participate by your doctor because you have no known eye conditions, you will be asked to come for 2 visits within 4 weeks. Each visit will take about 2 hours. If you were asked to participate by your doctor because you have eye conditions, you will be asked to return for 14 visits in the first year of the study, 9 visits in the second and third years of the study and 4 visits per year (2 visits every 6 months) until the end of the study. Total study duration for participants with eye conditions is up to 5 years. Each visit will take about 1 to 2 hours. You may be asked to come for additional visits to complete research required tasks or to do a specific test again.

The greatest risks of this study include the possibility of some discomforts, which are similar to those encountered in any complete eye examination, and potential for loss of confidentiality. It will be necessary to use numbing and dilating drops. Some risks include: dry eye, mild headache, blurred vision, drowsiness, burning eyes, tearing, light sensitivity, redness, and allergy reactions to the drops.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have any of the following conditions: glaucoma, non-glaucomatous optic neuropathy, age-related macular degeneration or other retinal degeneration, or a disease affecting the visual pathways (such as tumors, optic neuritis or ischemic neuropathy), or you are a participant with healthy eyes. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

Dr. Felipe Medeiros will conduct the study in collaboration with Professor C. Ross Ethier from Georgia Institute of Technology. This study is funded through grants from the National Institutes of Health (NIH) and funding from the Department of Ophthalmology.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Felipe Medeiros will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to better understand the impact of visual impairment caused by different eye diseases in the ability of patients to perform daily activities. The study aims at developing better tools to predict which patients are at higher risk of developing impairment and, therefore, to help in future patient management decisions.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 250 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. If you do not sign this consent form, you will continue to receive care, but not as part of this study.

We will also request that you sign a medical records release to allow us to have access to your medical records including general medical history, previous use of systemic medications, previous use of ophthalmological medications, previous eye examinations, previous eye procedures, and results of other medical tests.

Some tests and devices used in this study are used in standard clinical care and some are investigational. The word “investigational” means the study device is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

The items below will be done over 2 separate visits (visits “1” and “2”) within 4 weeks for all participants:

1. Measure of blood pressure, heart rate, height and weight.

2. Full ophthalmological examination that includes best-corrected visual acuity, contrast sensitivity measurements, slit lamp examination (careful examination of the front portion of the eye with a special light), dilated fundoscopy (examination of the back portion of the eye with a special light), a series of measurements of the eye pressure after drinking water, measurement of

the amount of lens opacity (cataract), evaluation and imaging (special pictures which do not require touching the eye) of the optic nerve and the retina, and visual field testing (testing of the peripheral vision). As with a regular complete eye examination, these tests require that the eyes receive special drops to numb the front portion of the eye (for the eye pressure testing) as well as to dilate the pupils.

3. Psychophysics (visual function tests) tests. These tests will be performed in order to better characterize the degree of visual function impairment (if any) you have, and how it relates to performance. They will include:

- Useful field of view exam. In this exam, the examiner will show you an image on a computer and ask you to identify the image.
- Series of tests on the screen of an iPad or similar tablet, including visual acuity, contrast sensitivity and acuity, visual processing speed and divided attention.
- Visual crowding. This test is also performed on a computer screen. You will be asked to identify a visual target presented under different conditions.

4. Visual Performance Eye Tracking test. During the visual tests, we will use devices that can monitor where you are looking. These devices are called eye trackers and they are like cameras that can monitor the position of your eyes. Different types of eye trackers may be used as part of this study, depending on the visual task performed, such as eye tracking glasses, monitors (Tobii instruments), and virtual reality goggles.

5. Brain wave testing (Electroretinogram – "ERG", Electroencephalogram – "EEG" and Visual Evoked Potentials – "VEP"). These are non-invasive tests that measure the electrical signals generated by your brain (brain waves) by placing small devices (called electrodes) that make contact with your hair or scalp and your lower lid. They will be measured by an FDA-approved device called Diopsys NOVA. Some preparation of your hair or scalp may be required in order to position the electrodes. The preparation includes cleaning the scalp with alcohol wipes and may also involve applying some gel for better contact. Your hair will not be altered or shaved, and gel can be easily removed with alcohol wipes. The test will monitor your brain waves while you perform visual tasks presented on a computer screen or monitor connected to a computer.

6. Driving simulation test. This test is similar to a computer video game. Using a panel of screens, a wheel drive, and a foot pedal, similar to a real car, all connected into a computer, you will control a virtual car and will be asked to do simple tasks, such as follow another car and keep up with the road speed. The results of driving simulation will not be reported to the Department of Motor Vehicles (DMV).

7. Virtual Reality Tests. These tests will be conducted using virtual reality goggles. You will be required to wear the goggles and will be presented with tasks that include scenarios replicating

daily activities such as driving on a road, walking through a virtual environment or searching for objects. In order to navigate through the environment, you will use a steering wheel or joystick.

8. Balance Assessment. For this test, you will be wearing head gear (special goggles) that will not allow you to see anything besides a visual world that will be projected in front of your eyes. You will be required to fixate or keep your gaze at the center of the scene, while different visual stimuli will be presented, such as rotating rings. During the test, you will stand on a specially designed platform, so that while you observe the screen, your body movements can be tracked. You will wear a harness to prevent you from falling.

9. Retinal metabolism evaluation (activity and health of the cells in the back of the eye): For this investigational test, a camera takes a photo from the back of your eye and measures the amount of a protein to evaluate the health of the cells in your retina (back of the eye). As with a regular eye photograph, the test is not invasive, but includes bright lights, which can cause mild discomfort.

10. Assessment of eye pressure with novel devices: This is a portable investigational device that measures the pressure of the eye with a rebound technique (that is, the tip of the device gently touches the eye for less than one second to measure the eye pressure). The contact of the instrument with the eye is gentle and takes place in less than one second, no numbing drops are needed, and patients typically do not feel the touch.

11. You will also be asked to complete questionnaires about:

- Sensitivity to motion sickness
- Pre- and post-simulation sickness
- Mental and physical health
- Daily driving habits
- Ability to find places or locations
- Socioeconomic status information
- History of falls and fear of falling using
- Cognitive Assessment or tests that measure how you think and process information
- Vision-related and glaucoma-related quality of life

All the procedures included in numbers 1 and 2 above are part of the standard ophthalmological care. However, the others are strictly study procedures which are being done because you are in this research study. The procedures in items 9 and 10 involve investigational devices, which means the study devices are still being tested in research studies and are not approved by the U.S. Food and Drug Administration (FDA).

The total expected duration of visits “1” and “2” above is approximately 2 hours each.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

If you are a participant with no known eye conditions, you will complete visits "1" and "2" only once during the study.

If you are a participant with eye conditions, you will be asked to repeat visits "1" and "2" every 6 months for up to 5 years. You may be asked to come for an additional visit if you cannot complete all of the testing during a scheduled visit. You may also be asked to come for an unscheduled visit if the study doctor needs to either repeat a test or for further evaluation. You will also be asked to come for 5 additional visits every 6 months for the first year of participation in the study, 5 additional visits for the second year of participation in the study and 5 additional visits at the beginning of the third year of participation in the study. In other words, you will have 7 visits every 6 months for one year, and then annually for 2 more years (Months 1, 6, 12, and 24 of your study participation. These visits (visits "3", "4", "5", "6", and "7") have an expected duration of 1 hour each. Visits "3", "4", "5", "6", and "7" consist of:

1. a series of measurements of the eye pressure, before or after drinking water,
2. evaluation and imaging (special pictures which do not require touching the eye) of the optic nerve and the retina, and
3. visual field testing (testing of the peripheral vision).

All the devices included in numbers 1, 2, and 3 above are approved by the FDA and are currently in use in standard ophthalmic (eye) care. However, these tests may not always be included in standard practice at the frequency that they will be done in this study.

The number of scheduled visits you will be asked to come are summarized in the chart below:

	Visits						
	Year 1		**Year 2**		**Year 3**		**Years 4 and 5**
Group	**Initial visit**	**At 6 months**	**Initial visit**	**At 6 months**	**Initial visit**	**At 6 months**	**Every 6 months up to 5 years**
Eyes with no known eye diseases	Visits "1" and "2"	None	None	None	None	None	None
Eyes with eye diseases	Visits "1", "2", "3", "4", "5", "6", and "7"	Visits "1", "2", "3", "4", "5", "6", and "7"	Visits "1", "2", "3", "4", "5", "6", and "7"	Visits "1" and "2"	Visits "1", "2", "3", "4", "5", "6", and "7"	Visits "1" and "2"	Visits "1" and "2"

You may be asked to come for additional visits to complete research-required tasks or to do a specific test again if necessary.

None of the eye procedures in this study are invasive. If you wear contact lenses, you may be required to remove them for certain eye procedures and before receiving study eye drops. Contact lenses must not be replaced until 30 minutes after receiving eye drops. Your study doctor will further explain this to you.

If any incidental findings are discovered during the ophthalmological exam, during visual function testing, or during the driving simulator or virtual reality testing, you will be verbally informed. If necessary, you will be referred to an appropriate specialist physician.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will last approximately 5 years if you have any eye conditions. If you are a participant with no known eye conditions, you will have only 2 visits within 4 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you, in written form, if the principal investigator believes that they may have the potential to affect the management or outcome of your medical condition.

WHAT ARE THE RISKS OF THE STUDY?
Risks from participating in the study are very low. As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose. The primary risks are some discomforts, which are similar to those encountered in any complete eye examination. You will undergo non-invasive procedures used for diagnostic purposes. Some tests are used in standard clinical care and some are not.

Eventually, it will be necessary to use numbing and dilating drops. These drops are routinely used during eye exams. Although rare, there may be side effects associated with these drops, as listed below:

- Blurred vision,
- Drowsiness,
- Headache,
- Stinging eyes,
- Burning eyes,
- Tearing,

- Light sensitivity,
- Redness, and
- Hypersensitivity reactions. Occasionally, people have allergic reactions to medications, which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.
- Numbing drops are considered safe during pregnancy or breastfeeding. However, for dilating drops the risks are currently unknown. You will not receive dilating drops as part of this study if you are a woman of childbearing potential or if you are pregnant or breastfeeding. Therefore, tests that require pupil dilation will not be conducted unless you have already received dilating drops as part of your eye care visit with your doctor.

You may experience mild discomfort due to drying of the eye during the study. If you note drying, a drop of artificial tear will be placed over the eye by the study key personnel. In very rare cases, artificial eye tear drops may cause irritation or allergy.

Psychophysics tests, EEG, eye tracking, driving simulation, virtual reality tests, balance assessment, retinal metabolism evaluation, and the use of investigational devices are not used in standard clinical care. The risks associated with these tests are described below:

- For psychophysics tests, EEG, eye tracking, and retinal metabolism evaluation: there are no known risks associated with the other than discomfort and fatigue.
- For virtual reality, balance assessment, and driving simulator tests: you may become bored, fatigued or distressed while participating in the virtual reality and driving simulator tests. To minimize these potential effects, the tasks will be kept short and you will be instructed that you may request to interrupt the test anytime. The driving simulator, virtual reality tests, and balance assessment may cause dizziness or motion sickness in susceptible patients. Every precaution will be taken to minimize this possibility of motion sickness (for example by limiting the speed of linear or rotational motion).
- For the VEP testing: there is a small risk that the VEP testing may cause a mild headache. There may also be an increased risk of triggering a seizure in people who have had seizures in the past.
- For the investigational device to measure the eye pressure: the device briefly touches the surface of the eye and there is a rare possibility of corneal abrasion (a scratch on the surface of the eye). This risk is similar to other devices that measure your eye pressure in standard clinical care.

There is, also a risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of

this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

In addition to the risks and discomforts listed here, there may be other risks that are currently not known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. You will receive a comprehensive eye examination and will undergo other tests that will allow a better understanding of the relationship between potential visual impairment caused by ophthalmological diseases and the ability to perform daily tasks. The results of the study are likely to provide important information on how eye diseases are associated with visual impairment, task performance and quality of life. This may lead to development of better tests to predict patient performance and visual loss, which could benefit patients with these diseases. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. Additionally, results of the tests you perform as part of the research study will be shared with the Georgia Institute of Technology (GA Tech) as part of a collaboration to develop specific software to measure specific areas of your eye. We will share only the minimum necessary information in order to conduct the research, and none of the information we share with them can identify you. Your personal information may also be given out if required by law.

As part of the study, results of your tests and procedures may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board, the National Institutes of Health (NIH) and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and procedures performed. Some of these tests and procedures would have been done as part of your regular care. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be

destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

The Cognitive Assessment test will be done in a tablet with a mobile application, in which you will answer to some questions, write and draw figures. The tablet is encrypted, updated frequently to a current operating system and is locked when not in use. The application is developed by MoCA Test Inc, Quebec, Canada. Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information from the device may be stored outside of Duke. The study team will limit personal identifiers entered into the mobile application to your initials, date of birth, and study number only to protect your privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Medeiros. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study will cover the cost for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will be compensated $30 for each visit as part of this study to help cover your time and parking and gas expenses (up to $450/year (calculated based on 15 visits per year)). You may be

asked to come back for an additional visit(s) to complete research tasks or to do a specific test again; if you are asked to come back for another visit, you will be paid an additional $30. You will be paid after each visit has been completed. The value will be added to your balance on a debit card the study team will provide to you, called ClinCard.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual totals $600 or more in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

If you are a Medicare, Medicaid or Tricare patient or you have no health insurance, and you are injured as a result of your participation in this research study you will get reimbursed or the provider of services for the medical care you receive for your injuries provided all aspects of the study protocol have been followed correctly and your injuries are not the result of the natural progression of your glaucoma or ocular hypertension. Medicare, Medicaid or Tricare will not be billed for these injuries.

If you have commercial (private) insurance, and you are injured as a result of your participation in this research study, your insurance provider will be billed for medical care you receive for these injuries. For any such costs that are not covered by your insurance provider you will get reimbursed or the provider of services for the medical care you receive for your injuries provided all aspects of the study protocol have been followed correctly and your injuries are not the result of the natural progression of your glaucoma or ocular hypertension.

For questions about the study or research-related injury, contact Dr. Felipe Medeiros at (919) 684-0201 during regular business hours and by calling the paging operator at (919) 684-8111 and asking for Dr. Medeiros after hours and on weekends and holidays.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Felipe Medeiros in writing and let him know that you are withdrawing from the study. His mailing address is 2310 Erwin Rd, Durham, NC, 27710. You will be asked to follow up with your eye care provider.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include:

- If you fail to follow directions while participating in the study;
- If you are unable to complete the testing required
- If your study doctor determines that it is no longer in your best interest to continue;
- For administrative reasons;
- If the regulatory agencies cancel or stop this study.

If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of visual and task performance in subjects with eye diseases
Investigator: Felipe Medeiros, MD, Ph.D

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Felipe Medeiros at (919) 684-0201 during regular business hours and by calling the paging operator at (919) 684-8111 and asking for Dr. Medeiros after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____	_____	_____
Witness	Date	Time