CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Surgical Idiopathic Intracranial Hypertension Treatment (SIGHT) Trial

STUDY DOCTOR'S INFORMATION

Name: [fillable field]
Contact Number: [fillable field]
Site Name: [fillable field]
Site Address: [fillable field]
Emergency (24-hour) Number: [fillable field]
Study Coordinator Name/Contact: [fillable field]

SUMMARY

This consent form will give you important information about this study. It will help you decide if would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

- The study is being done to find out how different treatments work to reduce or reverse visual loss in people who have a condition where the pressure inside the skull increases for no known reason. This is called idiopathic intracranial hypertension (IIH).
- You will be asked to be in the study for up to three years. The study will involve tests to make sure you are eligible. If you are eligible, you cannot choose your treatment group. A computer program will assign you to a treatment group. There are three treatment groups. One group will take diuretics ("water pills") that helps your body get rid of fluid. The main diuretic used in this study is called acetazolamide. It is not FDA approved for the treatment of IIH, but it is often used for this purpose by doctors. For this study, acetazolamide is considered an experimental drug, even though you can receive it even if you were not in this study. Another group will take diuretics and have a surgical procedure called optic nerve sheath fenestration (ONSF). It involves making a cut into the covering of the optic nerve (the nerve that transmits vision from the eye to the brain) to try to relieve pressure. The last group will take diuretics and have a surgical procedure called ventriculoperitoneal shunting (VPS). It involves placing a tube from the fluid area of the brain to the abdomen to try to lower pressure around the brain. No matter which of the three groups you are in, there will be vision and blood tests performed at study visits. You also will be asked to fill out surveys at several visits.
- There are a number of side effects from the study medication (including low energy, taste problems, loss of appetite, weight loss, frequent urination, tingling lips and limbs). The surgeries involve anesthesia. All surgeries have risks. The specific risks for these surgeries are described later in this document.
- The possible benefits are that your vision ***may*** not get worse or your vision ***may*** improve. However, this is not a guarantee. You will receive careful follow-up to check your vision. The research may help other people with IIH in the future.
- If you do not participate, you may receive any of the treatments being used in the study. You could also receive different medications or a different type of surgery.

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have idiopathic intracranial hypertension (IIH). IIH means the pressure in the fluid surrounding the brain is higher than it should be. The cause of IIH is unknown. It occurs most often in females who are overweight. IIH often causes headaches and swelling of the optic nerves. The optic nerve connects the eye to the brain. When it swells due to the pressure around the brain, vision loss can happen. We want to find out which treatment works best to reduce or reverse visual loss in people with IIH who have moderate to severe vision loss.

Your study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently. Also, your regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by doctors who are part of the Neuro-Ophthalmology Research Disease Investigator Consortium (NORDIC). The Jaeb Center for Health Research is coordinating the study. The study is being paid for by the National Eye Institute of the National Institutes of Health. The funding will be used to organize the study and to pay your study doctor's office for their work on the study. Your study doctor and clinic staff will carry out this study. The name of the study doctor and the doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the drug in this study, then they have to tell the Jaeb Center. The Jaeb Center has a policy to make sure that study doctors cannot work on this study if they get money or benefits that would influence how they do the study.

WHY IS THIS STUDY BEING DONE?

When vision loss from IIH is moderate to severe, several medications and surgical treatments can be used. Although each of these treatments can be effective, doctors are still not sure which treatments work best. The purpose of this study is to find out which treatment works best to reduce or reverse visual loss in people with IIH. We expect that about 180 people will take part in this study from about 40 different medical centers in the United States and Canada. If you agree to take part in this study, your involvement will last for up to three years.

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you **must**:

- have IIH with moderate to severe visual loss in one or both eyes

Also, you **must not**:

- be currently taking certain medications to treat IIH, including corticosteroids, topiramate, and diuretics (other than furosemide)
- have had previous surgery for IIH
- have any treatments for IIH outside of the study, such as weight loss surgery, during the first six months of the study
- **be pregnant**
    - If you are a woman who has the potential to get pregnant, we will do a test to be sure you are not pregnant before you enter the study. This will not be necessary if your last period was two years or more ago or if you have had a hysterectomy or tubal ligation. If you have the potential to become pregnant, you will need to use a form of birth control during the first six months of the study. *Acceptable approaches include use of oral contraceptives, transdermal contraceptives (patches), diaphragm, intrauterine devices, condoms with spermicide, documented surgical sterilization of either you or your partner, or abstinence.*

If you are nursing a child, please speak with your doctor to discuss breastfeeding during the study.

Your study doctor and staff will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?
If you agree to take part in this study, your involvement will last for up to three years. There will be about 9-11 study visits. Further study visits may be required, depending on how you are doing.

Screening Visit
The Screening Visit will collect information from you and do testing to determine if you are eligible to take part in the study. The Screening Visit will take about six hours. Screening tests may be completed over multiple days.

The Screening Visit will include a review of your medical history, eye exams, at least two tests of your side vision, pictures of your eyes after inserting eye drops, physical exams, blood tests, pregnancy test for females, and questionnaires. You will have blood drawn as part of your usual care.

- If you agree, we also will draw blood (~20 ml or about 4 teaspoons) to use for further research. The blood samples might be used by researchers to evaluate for genetic, hormonal, and metabolic factors associated with IIH.

In addition, you may need to have other tests done to confirm the diagnosis of IIH. These tests would be needed even if you are not in this study. The tests include magnetic resonance imaging (MRI scan) and lumbar puncture (LP).

- An MRI takes pictures of your brain.
- An LP involves numbing of the skin over the low back and inserting a thin needle into the sac of fluid below the spinal cord. A tube is then attached onto the needle to measure the pressure. Some spinal fluid is removed for laboratory tests. The testing is done to

make sure that you do not have another cause for high pressure, such as an infection or inflammation. If you have not had a recent LP, or if the pressure was not measured, the study doctor will arrange to have it performed. In that case, the procedure will be explained to you and you will sign a separate, standard consent form for the procedure. Generally, about 15-20 ml (4 teaspoons) of spinal fluid will be removed to temporarily lower the pressure. About 6 ml are needed for routine laboratory studies.

Study Treatments

If you are eligible to be in the study, the next step will be to determine your treatment group. You cannot choose your treatment group. This will be done with a computer program by a process similar to pulling a name out of a hat. You will have an equal chance of getting one of three treatments.

The three treatments are:

(1) medicine (water pills) and diet instructions only
(2) medicine (water pills), diet instructions, and optic nerve sheath fenestration surgery (making a small cut on the outside of the eye-related nerve)
(3) medicine (water pills), diet instructions, and ventriculoperitoneal shunt surgery (putting in the tube from the fluid area of the brain to the abdomen)

If you are going to receive a surgical treatment, there may be additional tests needed as part of your standard care.

The study team will instruct you in a low-sodium, weight loss diet. They may recommend a consultation with a dietician or referral to a medical weight loss program. If you are overweight, the goal will be to lose at least 6% of your initial body weight in 6 months.

For medicine, you will be asked to take acetazolamide (water pills) twice a day. It is often used for the treatment of IIH, but it is not approved by the Food and Drug Administration for this purpose. Therefore, acetazolamide is considered an experimental drug for treating IIH, even though you can receive it without being in this study. The dose will be increased over time. You could be taking up to 16 of these pills a day. If you have too many side effects, the study team will work with you to decrease the dose. If you cannot tolerate acetazolamide at any dose, it will be discontinued. Instead, you will be given a prescription for another kind of diuretic (water pill) called furosemide. Also, if your vision worsens or other symptoms are a problem while taking acetazolamide, you will be given a prescription for furosemide to add to your treatment. You will be asked to take furosemide twice a day too. The dose will also be increased as needed. You will be monitored while you are taking these medications to help make sure you are safe and well.

Your doctor(s) may give you other medications to help treat your condition.

<u>Optic Nerve Sheath Fenestration (ONSF)</u>

The optic nerves carry information from the eye to the brain. They are surrounded by fluid. The fluid is surrounded by a tough covering called a “sheath”. During the surgery, the surgeon will cut a window in the covering. This lets some of the fluid leak out into the area behind the eye.

ONSF is thought to improve vision by lowering the pressure on the optic nerve. The surgery will be described to you in detail by your surgeon. You will have an opportunity to ask questions.

You will be admitted to the hospital for the surgery. The surgery is performed under general anesthesia. A cut will be made either through the crease above the upper eyelid or near the bridge of the nose. The surgery takes about an hour per eye. Your surgery may be video-recorded for the study team to review.

You will stay in the hospital overnight. You may be discharged the next day if there are no complications.

If both your eyes are eligible for the study, ONSF will be performed on the eye with worse vision first. If only one eye is eligible, the surgery will be performed first on that eye. Sometimes ONSF on one eye helps the other eye. If this happens, surgery on the other optic nerve may not be needed. The need for surgery on the other optic nerve will be decided about 2 weeks after the first surgery.

If your vision and optic nerve swelling improve after surgery, your study doctor may start to decrease the dosage of the medicines (acetazolamide, furosemide or both).

Ventriculoperitoneal Shunting (VPS)
The optic nerves are surrounded by the same fluid that circulate in spaces inside the brain called ventricles. VPS drains fluid through a tube from the ventricles into the abdomen where the fluid is absorbed. VPS is thought to improve vision by decreasing the fluid pressure in the brain and surrounding the optic nerves. The surgery will be described to you in detail by your neurosurgeon. You will have an opportunity to ask questions.

You will be admitted to the hospital for the surgery. The procedure is performed under general anesthesia. A brain scan (MRI or CT scan) will be done to precisely map the location of the ventricle that will be shunted (usually on the right side of the head). Prior to surgery, some of your hair will be shaved near the surgical site. While you are asleep, the neurosurgeon will cut through the skin to see the skull bone. Then a hole will be drilled in the skull about the size of a nickel. A small plastic tube will be put into the hole and through the brain into the ventricle. Then, a long piece of tubing will be tunneled under the skin into the abdomen. Your surgery may be video-recorded for review by the study team.

You will be monitored carefully in the hospital. You may be treated with pain medications, antibiotics or both. If there are no complications, you usually will go home the next day.

Your study doctor may start to decrease the dosage of medicines (acetazolamide, furosemide or both) on the day of this surgery.

Follow-up Visits and Testing
You will be asked to return for follow-up visits at 1 week, 2 weeks, 1 month, 2 months, 4

months, 6 months, 1 year, 2 years, and 3 years after you get your treatment group assignment. Additional visits may be scheduled depending on how you are doing.

You will also receive phone calls from the study staff (at 3 months, 5 months, and 9 months) and from the Jaeb Center staff (about every 3 months after the 1 year visit).

When you are taking acetazolamide, you should bring the bottle(s) with your unused tablets to every visit. At the follow-up visits the following may be done: medical history updates, eye exams, physical exams, questionnaires, blood tests, tests of your side vision (visual field test), and photos of your eyes. When necessary, your doctor may decide to repeat tests of your side vision during the study.

You will be asked to undergo another lumbar puncture (LP) at the 6-month visit. This is often done as part of standard care, but it will be optional. This is to find out if the treatment has affected your fluid pressure levels. The procedure and fluid collection will be the same as at your screening exam.

The table below shows what will happen at each follow up visit:

Visit	Medical History Update	Eye Exam	Vital Signs	Questionnaires	Visual Field Test (side vision)	Eye Photos	Blood Tests	OCT[1] (eye images)	LP[2]
1 week	X	X	X		X			X	
2 weeks	X	X	X		X	X		X	
1 month	X	X	X		X	X		X	
2 months	X	X	X		X	X		X	
4 months	X	X	X		X	X	X	X	
6 months	X	X	X	X	X	X	X	X	X
1 year	X	X	X	X	X	X	X	X	
2 years	X	X	X	X	X	X	X	X	
3 years	X	X	X	X	X	X	X	X	

[1] Ocular coherence tomography, [2] Lumbar puncture (recommended but not required)

WHAT ARE THE RISKS OF THIS STUDY?

General Risks

Because of the amount of your vision loss, there is a chance that your condition will worsen. This could occur whether or not you participate in the study. Your vision will be monitored carefully throughout the study.

Risks of Examination
The risks of the examinations and testing are the same as those associated with an eye, neurological, and general medical examination in your doctors' offices. There is a possibility of irritating the front surface of the eye from either the eye drops or the eye pressure check. If this occurs, it usually gets better within several hours. Your reading vision will be blurred and you will be light-sensitive for several hours after receiving the dilating drops. Your eyes may be "dazzled" by the bright light used to take the photographs, but the light will not damage the eyes.

Risks of Lumbar Puncture (LP)
The risks of the LP include discomfort, bruising, minimal bleeding, brief back pain, and allergy to the local anesthetic or to the antiseptic used to clean your skin. Extremely rare complications include bleeding around the spinal nerves or a herniated disc. You must tell your study doctor if you are allergic to local anesthesia (lidocaine) or to iodine. About 20% of patients having an LP develop a headache after the procedure. The headache generally starts within the first 3 days after the procedure. The pain is worse when standing and is better when lying down. If you develop a headache after the LP, the study doctor will recommend treatment, which may include drinking fluids, caffeine, pain medicine, or a blood patch at the LP site (injecting your own blood into the lower back to stop the fluid from leaking out). No additional risk beyond that of usual care is expected.

Risks of Blood Draw
The risks of drawing your blood are bruising, lightheadedness, and a low risk of infection.

Risk of Collecting Genetic Information
The study may collect and use your blood to learn more about how diseases occur more in some families than in other families. It may also be used to learn about why some medicines work better or have more side effects in some people than in other people. It is possible that others could misuse this information.

A federal law called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Risks of Questionnaires
It is possible that some of the questions on the various rating scales might embarrass or upset you. The format is self-assessment, but you do not have to answer any questions that make you feel uncomfortable.

Risks to Confidentiality
This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of

confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

Risks of Acetazolamide

The table below lists the severity and relative frequency of possible side effects from acetazolamide.

Frequency of Risk	Risks that may be mild	Risks that may be more serious	Risks that may be life-threatening
More likely: happens with more than a third of people taking this drug	• Low Energy • Taste Problems • Loss of Appetite • Weight Loss • Tingling Lips and Limbs • Frequent Urination		
Less Likely: happens with a about a third or less of people taking this drug	• Depression • Kidney Stones • Drowsiness • Diarrhea • Increased Blood Acidity	• Low Blood Sodium	
Rare: happens in less than 1% of people taking this drug	• Ringing in the Ears • Nearsightedness • Sun-Sensitive Skin	• Low Blood Count • Low Blood Potassium • Kidney Failure • Allergic Skin Condition • Muscle Weakness • Abnormal Liver Function	• Severe Allergic Reaction

Risks of Furosemide

Furosemide causes frequent urination. It can lead to loss of potassium from the body. This requires monitoring of your blood. You will be prescribed potassium replacement, if needed. The most common side-effects of low potassium levels are fatigue and muscle cramps. Very low or very high potassium levels may cause your heart to beat abnormally and can cause a heart attack or death. Furosemide also may lower your blood pressure, causing lightheadedness or, in extreme cases, fainting. Some people are allergic to furosemide. The most common allergic reaction is rash.

Risks of Optic Nerve Sheath Fenestration

There may be temporary swelling or bruising of the eyelids and the area around the eye. The eye area may be painful for several days. If the eye socket is entered next to the bridge of the nose, the white part of the eyeball will be bloodshot for several weeks after surgery, the eye may feel irritated, and you may experience double vision. The double vision usually gets better on its own,

but sometimes eye muscle surgery is needed if it does not resolve. As the surgery is being performed near the optic nerve, there is a very small chance that your vision could worsen after the surgery. There is a smaller possibility of blindness in the operated eye (despite the surgery). There is a small risk of local eye infection.

Risks of Ventriculoperitoneal Shunting
You should expect to have pain around the incision site after the surgery. There is a small risk of infection, which may occur at any time after the shunt is inserted. An infection could lead to meningitis, which may be life threatening. This requires immediate treatment with intravenous antibiotics and removal of the shunt. The shunt tubing or valve can clog or break at any time, and your shunt will stop working. In this case, the pressure in your head may rise again, causing worse vision and headache. If this happens, you may need another operation to fix the shunt. If the catheter in the abdomen touches your internal organs, pain or discomfort can occur. This is rarely severe enough to remove or move the tube.

Risks of General Anesthesia
If you have Optic Nerve Sheath Fenestration (ONSF) or Ventriculoperitoneal Shunting (VPS) surgery, you will have general anesthesia. General anesthesia involves medications that are injected into the blood or breathed into the lungs. A tube or device is inserted into your airway to help you breathe. You will be unconscious. You won't feel pain during the procedure. The anesthesiologist will discuss the risks in detail. You will sign a separate consent form for anesthesia. Minor complications are injury to the lips, gums, teeth, vocal cords, and throat discomfort. Rare but serious risks include blood clots, nerve damage with weakness or loss of sensation, cardiac arrest, stroke, paralysis, permanent organ damage, brain damage, and death.

Risks for Women
The risks of acetazolamide on an unborn baby or a nursing child are unknown. For this reason, women who become pregnant during the first six months of the study will be asked to stay in the study but will no longer receive acetazolamide. A pregnancy test is done as part of screening for this study. You will also be asked about how you plan to make sure that you do not become pregnant while in the study (like if you use birth control). You will also be asked about pregnancy at each visit. If you plan to nurse a child during the study, please talk with your doctor before you decide to do so.

Unknown Risks
It is always possible that anyone taking acetazolamide for the first time may have an allergic reaction. Also, there may be additional risks from the acetazolamide or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Please discuss the risks with your study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?
The possible benefits are that study treatment may keep your vision from worsening or improve

your vision. However, this is not a guarantee. You will receive careful follow-up during the study to check your vision. The research may help other people with IIH in the future.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?
If you do not take part in this study, you could still receive any of the treatments being used in the study. You also could receive treatment listed below:

- treatment with different medications including other diuretics (water pills) or steroids
- lumboperitoneal shunting (running a tube from the fluid filled space in the lower spine to your abdomen)

CAN I STOP BEING IN THE STUDY?
You can stop being in the study at any time. If you decide to stop being in this study, you will not be treated differently. Also, your regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- The doctors think that being in the study may cause you harm
- You experience an injury related to the study
- You need additional or different medication not allowed in the study
- You do not follow the study plan

If you are removed from the study or the study is stopped, you may continue to receive care like you normally would if you were not in this study.

The entire study could be discontinued at any time by the Study Director, the National Eye Institute/National Institutes of Health, the Institutional Review Board, or the U.S. Food and Drug Administration (FDA) if the safety of research subjects is found to be at significant risk. If your participation in the study ends for any reason, you may be asked to return for a final study visit to complete a neurological and visual exam.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?
The costs of routine treatment, office visits, and tests that are part of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. All of the following medications, tests, and procedures are your or your insurance company's responsibility:

- Acetazolamide after the first 6 months of the study

- Other medications and supplements that you may be prescribed or used during the study. This includes furosemide, potassium, and headache medicines.
- Surgical procedures including ONSF and VPS and related hospitalizations
- Standard of care tests (any tests or exams for your condition you would have even if you were not participating in a research study):
    - neuro-ophthalmologic examinations
    - routine laboratory tests
    - visual field testing (not including repeat testing)
    - MRI or CT scan
    - initial lumbar puncture
    - optic disc photographs at the Screening Visit, 6-month Visit, yearly visits after 6 months, and any unscheduled visit

Testing that is specifically for this study will be paid for by the study. The study will pay for:

- acetazolamide for the first 6 months of the study
- repeat visual field testing, as required by the study
- optic disc photographs at the 2 week, 1 month, 2 month, and 4 month Visits
- all optical coherence tomography (OCT)
- the lumbar puncture at the 6-month Visit
- dietary consultation
- vital signs at each study visit
- the pregnancy test at the Screening Visit (for women of childbearing potential)
- additional blood drawn at the Screening Visit for future IIH research

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive $50 per completed study visit (i.e., Screening, 1 week, 2 week, 1 month, 2 months, 4 months, 6 months, 1 year, 2 years, and 3 years) to cover the cost of your time and travel. You will not receive compensation for extra visits that are required as part of your normal care.

You may have trouble paying for some exams and tests if you do not have insurance. Also, depending on your insurance plan, it is possible that your insurance will not pay for some of the exams and tests listed in this form. If you qualify for financial assistance, the study will pay for the costs of study visits and surgery, but the study is only able to reimburse up to a certain amount ($1,890 for study visits, $38,500 for VPS, and $23,000 for ONSF; the VPS and ONSF amounts include fees for hospitalization, surgeon, and anesthesia costs). Costs for other tests, procedures, or therapies that are part of your usual care will not be covered by the study.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can.

The study will not provide costs for care or other expenses relating to illnesses or injuries. The costs of care for illnesses or injuries will be billed to you or your insurance company like they normally would. Your study doctor, the study doctor's office, the Jaeb Center, and the National Eye Institute/National Institutes of Health are not offering payment for lost wages, direct losses, or indirect losses.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify you.

Certificate of Confidentiality

This study has a Certificate of Confidentiality. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Purpose of Authorization
We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign the Protected Health Information Authorization at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and sharing of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this study.

Using and Sharing Your PHI
Your study doctor will collect information about you. This information includes things learned from study procedures as well as your name, address, date of birth, and information from your medical records. These are examples of identifiable information. A code number and your initials will replace your name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The study doctor's office will not share study results that can identify you except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your study PHI.

The following people may see or receive your information from this study:

1. The people who work for this doctor's office
2. The people who work for the Jaeb Center for Health Research, which is coordinating the study
3. The people who work for the Neuro-Ophthalmology Research Disease Investigators Consortium (NORDIC)
4. The doctors and other researchers who are involved in the study
5. Any review board that oversees human investigations rules for your doctor's office
6. Any federal agency that oversees clinical trials
7. If you have an adverse (unfavorable) event, the people outside this doctor's office who assist in your care.
8. National Institutes of Health (NIH/NEI) or its representatives (funding agency)
9. Data Safety Monitoring Committee (DSMC) (the committee that follows the study data for any safety and enrollment concerns)
10. Any laboratory that is receiving samples for the study
11. Reading centers that will be responsible for evaluating and grading visual field tests, OCT tests, and photographs.
12. A central lab which will store de-identified blood samples for future IIH research

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting.
Results from the study will be sent to you from your study doctor or clinic after the main paper is published in a journal.

Who Can Receive and Use Your Study Information?
It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that sponsor the study. In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). If so, people outside this doctor's office who assist in your care may see your study PHI. They may not be covered by the law. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

Other Considerations
The information and samples collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely.

A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify you.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you for the phone calls described earlier.

If your study center is not able to locate you when they try to schedule your follow-up visit, a third-party search service may be used to try to contact you.

If your surgery is video-recorded, the video will not be shared outside of the study. Also, it is very unlikely you could be identified by the video.

Clinical Trial Reporting
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. A copy of one of the study consent form templates will also have to be posted on a federal website.

Can You Cancel Your Authorization?
You may cancel your permission for the use and sharing of your study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study except when there is a safety concern related to the study. If there is a safety concern, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

When Will the Use and Sharing of Your PHI Stop?
Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first.

The rest of your study information does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name, address, telephone number, or social security number.

Identifiable Private Information for Future Use
Your information that is identifiable will be stored, maintained or used for future research as required by the NIH. The identifiable information that will be used is the images that we have taken of your optic nerves. This information will be publically available. Your images could be used for other research, to help design future studies, or for teaching materials.

Your identifiable private information may be stored and used indefinitely.

You will not be told about the specific future uses of your identifiable private information because they are unknown at this time. This means that you will not be told about the purpose of the future research. If there is a certain kind of research study that you would not normally want to do, you won't know if a future study is like that. Also, the results from the future studies will not be shared with you.

There are plans to protect your information by removing any dates, names, initials, or other information from the images that could make it easier to identify you. There is still a chance that a loss of that protection could occur. This would be a loss of confidentiality.

It is not expected that you will have any benefit by allowing your identifiable private information to be stored, maintained, or used for these future research purposes. You do not have to allow the study to store, maintain, or use your identifiable private information for future purposes if you don't want to. If you decide not to, you will not be treated differently, and you can still be in this study. Also, your regular care will not be impacted.

Please contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if:

- you have questions about your rights as a research participant
- you wish to talk about you concerns or suggestions about the storage, maintenance or use of your identifiable private information
- you want to know about future research studies, want additional information, or want to provide comments

Participant's Full Name (printed) _____

Study Participation and Protected Health Information Authorization

By signing below, you agree to take part in this study, and authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You cannot be in this study if you do not provide this permission. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you authorize the use and disclosure of your protected health information
- you freely choose to participate, you can withdraw at any time, and you will receive a copy of this consent form

_____ _____
Participant Signature Date

Additional Blood Collection for Future Research

☐ **Yes** ☐ **No** By checking "yes" you are agreeing to have an additional ~20 ml (about 4 teaspoons) of blood drawn at the Screening Visit to be used for future IIH research. You can still be in this study if you do not provide this permission.

_____ _____
Participant Signature Date

Permission for Identifiable Private Information for Future Use

☐ I ***do*** give my permission to allow for the storage, maintenance, and use of my identifiable private information from the images that have been taken of my optic nerve as described above, or

☐ I ***do not*** give my permission to allow for the storage, maintenance, and use of my identifiable private information from the images that have been taken of my optic nerve as described above

_____ _____
Participant Signature Date

Investigator's Certification

I certify that to the best of my knowledge the participant understands the nature, demands, risks, and benefits involved in the participation of this study.

_____ _____ _____
Investigator's Printed Name **Investigator's Signature** **Date**