CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Randomized Clinical Trial Assessing the Effects of Pneumatic Vitreolysis on Vitreomacular Traction (Protocol AG)

STUDY DOCTOR'S INFORMATION
Name:
Contact Number:
Site Name:
Site Address:
Emergency (24-hour) Number:
Study Coordinator Name/Contact:

SUMMARY
This consent form will give you important information about this study. It will help you decide if you 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.

- **You have a condition called vitreomacular traction (VMT). VMT is a condition of the retina of the eye that can affect vision.**

- **The study is being done to see if an injection of a gas bubble into the eye works to resolve VMT. Half of the study participants will receive one injection of a gas bubble into the eye. The other half will be observed to see if the VMT gets better on its own.**

- **You will be asked to be in the study for about 6 months. There will be five office visits. At the visits you will have vision testing, an eye exam, and imaging of your eye.**

- **The most likely risks to you from the treatment are eye pain, discomfort, redness or itching, and floaters. For some people the gas bubble may be visible for several weeks and at times may completely block vision. Rare but serious risks include bleeding in the eye, rise in eye pressure, macular hole, retinal tear or detachment, cataract, or endophthalmitis (infection of the eye).**

- **The possible benefits are that the treatment may help restore or improve vision, while avoiding surgery. However, that is what the study is trying to find out. People who take part in this research study will add to new knowledge that may help other people with the same problem.**

- **If you do not participate, you may wait to see if the VMT goes away on its own, have surgery, have a gas bubble injection outside of the study, or have an injection of Jetrea®, which is an FDA-approved medicine for treatment of this condition. Your eye doctor can give you more information on all of these options.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have vitreomacular traction in at least one of your eyes. We will refer to this as VMT. The vitreous is the clear, gel-like substance that fills the inside of the eyeball. The macula is the center part of the retina that is used for sharp, straight-ahead vision. In VMT, the vitreous is abnormally attached or stuck to the macula. As the vitreous gel separates from the retina due to normal aging, the abnormal attachment can lead to traction or pulling on the macula. The pulling causes swelling and abnormal elevation of the macula that leads to a decrease or distortion in vision. The goal of this study is to learn whether the injection of a gas bubble into the eye can help people with vitreomacular traction by relieving the traction on the macula.

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, your regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by the DRCR Retina Network, which is a group of clinical sites dedicated to research of retinal diseases. It is being paid for by the National Eye Institute (NEI), one of the National Institutes of Health of the U.S. Public Health Service, a part of the federal government. The Jaeb Center for Health Research is the Coordinating Center for the study. They will use the funding 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 get money or benefits from a company that makes the treatment 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?

Current treatments for VMT include surgery to remove the vitreous ("vitrectomy") which will relieve the traction, an injection of ocriplasmin (Jetrea®), or waiting to see if the VMT resolves on its own. The purpose of this study is to find out if another treatment using injection of a gas bubble into the eye results in release of VMT more often than observation. The gas is called perfluoropropane or C_3F_8. Injection of the gas bubble has been used in some patients with VMT to try to cause release of the traction sooner than watching and waiting. However, it is not known for sure that the gas bubble injection is better than just waiting to see if the VMT goes away by itself. Based on prior studies, we think VMT resolves on its own about 10% of the time in the first month and about one-third of the time within 18 months. We think that the resolution rate will be higher with the gas injection but the injection also has possible risks.

WHO CAN PARTICIPATE IN THIS STUDY?

First, testing will be done to find out if you are eligible for the study. If both of your eyes have VMT and are eligible for the study, you and the eye doctor will select one eye to be included in the study. The other eye not in the study cannot receive a gas injection during the study. We will refer to an eligible eye as a ***study eye.***

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

- Be 18 years or older
- Be able and willing to avoid high altitude travel for up to 8 weeks.
- Be able and willing to avoid lying on your back for up to 8 weeks.
    - Note: if the eye with VMT has had cataract surgery, then this is not necessary.
- Be willing to wear a wristband for up to 8 weeks notifying healthcare professionals that a gas bubble is present in the eye.
- Have VMT that meets certain criteria
- Have impaired vision that is mostly likely caused by the VMT

Also, you must not:

- Have another eye condition in the study eye that may affect your vision or need treatment during the study
- Have had previous injections in the study eye for any reason
- Have had previous vitrectomy surgery in the study eye

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

We expect about 130 people will take part in this study at about 50 different medical locations.

WHAT WILL HAPPEN IN THIS STUDY?

A. Screening for the Study

We will ask you questions about your medical history and previous eye problems and treatment. Then, some tests will need to be completed, if they have not already been done, to find out if you are eligible for the study. The tests include:

1. **Vision Testing**
    - This will include measurement of your visual acuity (the ability to read letters on the vision chart) using an electronic tester. This measurement will be done for each eye separately.
    - Visual function will be tested using an app called myVisionTrack® on your clinic's iPad or tablet. myVisionTrack is an FDA approved method for monitoring the progression of degenerative eye diseases. The app will display a series of three side-by-side circles on the screen, and you will select the circle that is shaped differently. The test takes about 5 minutes.

2. **Eye Exam**
   - An eye exam will be performed. The structures inside the eye will be examined through a special microscope after drops have been placed in your eyes to dilate your pupil. The pressure in your eye will be measured. The doctor also will press on the outside of your eye while looking at your eye. This is called a scleral depression. This test helps the doctor see parts of the eye that are difficult to see. The eye exam will be completed on both eyes, even if only one eye is being evaluated for the study.

3. **Optical Coherence Tomography**
   - Optical coherence tomography (referred to as OCT) uses a dim beam of light to measure the structures of the retina and the optic nerve. You will look into a machine at a pattern of flashing and rotating red lights. This test is done to make sure you have vitreomacular traction. During the study, OCT will be used to find out if and when the vitreomacular traction releases. OCT will be done on both eyes, even if only one eye is being evaluated for the study. The OCT will be sent to a central reading center that will confirm you are eligible for the study.

4. **Laboratory Tests**
   - If there is any chance that you might be pregnant, a pregnancy test will also be done.

B. Study Treatments

If you are eligible and agree to take part, we will then determine whether your study eye will receive:
1) Injection of a C_3F_8 gas bubble at the start of the study OR
2) Observation

If you decide to take part in this study, a computer program will be used to select whether you will be in the Injection group or Observation group. This is like flipping a coin to decide in which group you will be. There is an equal chance of being in each group.

You will not know which treatment you are receiving. This information is available in the event of an emergency.

Injections into the eye of C_3F_8 gas have been approved by the U.S. Food and Drug Administration for a procedure called pneumatic retinopexy, which is a treatment for certain types of retinal detachment. These C_3F_8 gas injections into the eye have been used by retina specialists for more than 30 years to treat retinal detachment. Gas injections have not been approved for treating VMT. Therefore, gas injections in this study are considered experimental.

If you are in the Observation Group, you will receive a *sham* injection at the start of the study. "Sham" means that no actual injection is given. The sham injection will be given as similarly as possible to a real injection. The difference is that a needle will not go into the eye. You will not know whether you are receiving a "sham" injection or real injection. This is called "masking." Masking study participants is important to get better information about the risks and benefits of each treatment group being studied.

Prior to both a real injection or sham injection, an antiseptic solution will be used to reduce the chance of infection. Then, an anesthetic injection may be given under the surface of your eye for additional numbing, if needed.

In the Injection group, C_3F_8 gas will be injected into the eye. If you are in the Observation Group, a sham injection will be given.

An additional procedure may be performed in which a needle is used to remove fluid from the eye either before or after the injection to avoid or relieve pressure in the eye. This procedure is called paracentesis. Your doctor will decide if this is needed.

Optional Sample Collection:
With your permission, fluid removed from the eye during pre- or post-injection paracentesis (if performed) may be stored and used for future research. Further information on this optional sample collection is provided later. You can decide not to allow your sample to be used for future research and still be in the study.

After the injection, you will stay in the eye clinic until your doctor believes it is safe for you to leave. You will need to avoid large increases in elevation from where you receive the injection until the gas bubble goes away (about 6 to 8 weeks). This includes air travel. You should also avoid travel to a higher elevation or over mountain ranges. You do not need to avoid travel to a lower elevation. You will also need to avoid lying on your back until the gas bubble goes away. You should not receive nitrous oxide anesthesia until the gas bubble goes away. Your doctor will give you a wristband to wear that will notify healthcare providers of this. Your eye doctor will tell you when it is safe to resume normal activity and to remove the wristband.

C. Follow-Up Visits
You will be in the study for 6 months. Four follow-up visits will take place on or after 1 week, 4 weeks, 12 weeks, and 24 weeks. If during the study, your condition worsens, surgery may be done to remove the vitreous and relieve the traction. Any surgery will not be part of the study. Your doctor will report surgery that happens up to 12 weeks after your participation in the study ends.

In the following table you will find what will be done at each visit.

	Initial Visit*	1 and 4 weeks	12 and 24 weeks
Electronic visual acuity testing in both eyes	X	X	X
Visual function testing (myVT®)	X		X
OCT [a]	X	X	X
Eye exam [a]	X	X	X
Treatment (gas or sham) in the study eye	X		

* All testing does not need to be on the same day but must be within 8 days prior to entering the study
a=both eyes at baseline; study eye only at each follow-up visit

WHAT ARE THE RISKS OF THIS STUDY?

If you decide to take part in the study, you will be at risk for the side effects listed below. We encourage you to discuss these with your study doctor, your primary care provider, or another health care professional. If a treatment or procedure has increased risks because it was not done according to study procedures due to error, you will be informed, and the necessary steps will be taken to care for you.

Risks of Eye Examination and Tests

1. **Vision Testing:** There are no known risks associated with using the electronic vision testing.

2. **Eye Exam:** As part of the eye exam, drops will be put in your eyes to dilate the pupils. The drops may blur your vision and make you sensitive to light. The drops will wear off over several hours. There is a small risk of an allergic reaction to the drops. There is also a small risk that the drops could cause the eye pressure to rise. If this happens, it will be treated, but there is a small risk of losing vision from the pressure rise. Due to the blurring effect on your vision and possible light sensitivity, we recommend that you do not drive until the blurring effects of the drops have worn off. If necessary, have someone come with you who can drive for you after the exam. When the doctor presses on your eye, the pressure can be uncomfortable.

2. **OCT:** There are no known risks associated with OCT.

Risks of Injection Preparation (for Sham and Gas Injections)

- The antiseptic solution may cause discomfort, redness, or itching.
- It is unlikely that the drugs used to numb your eye before the study drug injections (proparacaine, tetracaine, or xylocaine) will cause any problems. However, in rare instances, these drugs can cause an allergic reaction, seizures, and an irregular heartbeat. A serious allergic

reaction occurs in less than 1 in 100,000. Your doctor will monitor any effects these drugs may cause and treat them as necessary.

- In addition to topical numbing drops your doctor may also give you a tiny injection of xylocaine to numb your eye before the study drug injection is given. You may feel a temporary stinging sensation from the xylocaine injection. If an injection is given, in very rare instances the injection can cause damage to your eyeball, damage to the optic nerve, or double vision lasting up to 24 hours or more. Once your eye feels numb, you may still be able to feel touch or pressure within your eye, but you should not be able to feel pain. Sensation usually returns within four hours.

Risks of Gas Injection

The more common side effects that are known:

- Pain, discomfort, redness, or itching lasting for a few days is likely.
- Subconjunctival hemorrhage (bleeding under the surface of the eye because of a broken blood vessel) is common after the injection. It is usually minor and clears naturally from a few days to a week or two. It has no effect on vision.
- Floaters will commonly occur as a result of the injection. For some people the gas bubble will be visible for several weeks and may at times block vision **(**you may or may not see the gas bubble). You may also have a temporary loss of depth perception. The floaters are typically reduced after 6-8 weeks, but some floaters may persist.
- Right after the injection, there may be a rise in pressure inside the eye. It usually goes back to normal on its own, but may need to be treated with drugs or a paracentesis to lower the pressure. The likelihood of permanent loss of vision from elevated intraocular pressure is less than 1 in 100.
- If vitrectomy is required while the gas bubble is still present in the eye, there is a very high likelihood of cataract development during the surgery. Vitrectomy would only be performed if your vision worsens or you have a complication that requires surgical intervention. If a cataract does develop during vitrectomy, it is typically taken care of by replacing the lens at the time of vitrectomy.

The less common side effects that are known:

- Complications associated with paracentesis (if performed) are uncommon, but may include leakage of fluid from the front of the eye, bleeding, inflammation, and change in the pressure inside the eye. Under certain circumstances, such complications may lead to vision loss. Treatment of above conditions can be performed to reduce vision loss.
- There is a possibility of immediate cataract development from paracentesis (if performed) or the gas injection. The risk of developing a cataract right away is less than 1%. If a cataract develops, cataract surgery may be needed. In most cases, this surgery is successful in improving vision.
- As a result of the injection, infection inside the eye (known as endophthalmitis) could develop. If this happens, it is treated by injection into the eye of antibiotics alone or with surgery, but there is a risk of permanent loss of vision including blindness. Endophthalmitis has not been reported in prior small studies of this treatment, but it is possible. Endophthalmitis occurs in less than 1% of injections from other types of injections into the eye.

- As a result of the injection, a retinal tear or detachment could occur. If a retinal tear occurs, laser or a freezing treatment, which is usually performed in the office, may be required. If a retinal detachment occurs, surgery in an operating room may be needed to repair the retina. The treatment is usually successful at repairing the retinal tears or reattaching the retina. However, a retinal detachment can produce permanent loss of vision and even blindness, under certain circumstances. The risk of retinal tear and/or detachment after gas injection is about 5-13%. The risk of retinal detachment is higher if you already have certain retina conditions. **Please talk to your study doctor to find out if you have one of the conditions that would place you at higher risk.**
- There is a possibility that the traction gets worse instead of better after gas injection. If the traction gets worse, it may result in a macular hole. This has happened in less than 5% of cases in previous small studies.
- A type of inflammation in the eye called uveitis may develop after gas injection. Uveitis can be successfully treated with steroid eye drops, injections, or pills. However, uveitis can lead to permanent loss of vision if not treated early. Persistent uveitis is uncommon.
- Bleeding in the eye after gas injection is uncommon but may occur occasionally after gas injection, particularly given a history of active anticoagulation therapy or prior risk for bleeding. If present, it usually resolves from a few days to a few months. Serious bleeding requiring surgery after gas injection is very rare (less than 1%).
- The development of excessive scarring on top of or under the retina after gas injection is very rare (less than 1%). When this occurs, it is usually associated with advanced retinal detachment, which is also uncommon after gas injection.
- Loss of vision or blindness is possible if nitrous oxide anesthesia is administered with the gas bubble present in the eye. It is important that you follow the post-injection instructions and avoid nitrous oxide until your eye doctor confirms the gas bubble is gone.
- Large increases in elevation may cause the pressure inside your eye to increase, which may cause loss of vision or blindness. It is important that you follow the post-injection instructions and avoid high altitude travel until your eye doctor confirms the gas bubble is gone.
- Incorrect head positioning after injection may cause the injection to be unsuccessful or lead to glaucoma or cataracts.

Risks of Observation (Sham injection)

- There is a possibility that the traction gets worse over time, which may result in a macular hole or vision loss. Surgical intervention may be required to repair the macular hole or release the traction.

<u>Unknown risks</u>

It is always possible that anyone receiving a treatment for the first time may have an allergic reaction. Also, there may be additional risks from the treatment 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.

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 for women

The risks of the gas injection in this study on an unborn baby are unknown. For this reason, women who are pregnant cannot be in this study. Urine pregnancy tests are done prior to enrollment for females of child bearing potential. Women who become pregnant during the study will be asked to stay in the study since there is no follow-up treatment with the investigational product.

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 the treatment may help restore or improve vision, while avoiding surgery. However, that is what the study is trying to find out. People who take part in this research study will add to new knowledge that may help other people with vitreomacular traction.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include surgery to remove the vitreous ("vitrectomy") which will relieve the traction, a gas bubble injection outside of the study, an injection of FDA-approved ocriplasmin (Jetrea®), other research studies, or you may choose not to do anything. Your study doctor will discuss these choices with you.

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

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.

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. The 12 and 24 week visits are considered standard care visits. You or your insurance company will be billed for the OCT and eye exam at these visits. The study will pay for vision testing at all visits, as well as the OCT and eye exam at the all visits other than at 12 and 24 weeks.

The study gas injection will be provided to you at no cost. Any additional tests and procedures not listed above will be billed to you or your insurance company like they normally would.

Depending on your insurance plan, it is possible that your insurance will not pay for some of the procedures and testing required for the study; if they do not pay, the study may become responsible for these costs if you have a financial hardship. By signing this form, you certify that you understand that not all of the tests and procedures will be paid by the study and that you are aware that you or your insurance company will be charged for standard care procedures.

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 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.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $175 for your participation. These payments will be paid as follows: $25 for each completed visit prior to 24 weeks (up to 4 visits), and $50 for the completed 24 week visit. You will also be provided an additional $25 if you need to return on a separate day after the baseline visit to receive the assigned injection. These payments will be made by gift or money cards given to you by your study doctor's office. If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury.

You may be asked to repeat a testing procedure (OCT for example) if the study staff cannot use your data. If repeating the procedure requires you to schedule a doctor's visit outside of normal care, you will be provided an additional $25 gift or money card.

The study may reimburse you for travel expenses, if you have specific additional travel expenses above $25 that make it difficult for you to return for study visits.

If you agree to the optional sample collection at the time of the injection procedure, the use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

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

The National Institutes of Health has guaranteed a Certificate of Confidentiality for this study. 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 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.

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 in a letter when they are made public.

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, the central reading center, other sites in the study, and other investigators who help run the study. Vital Art and Science (VAS), the company who makes the visual function testing application, will store your test results and may use them in future publications. VAS may also store your birth date for login purposes. However, they will not collect any other personal information. 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 eye fluid 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. The study results will also be made public. These

results will not have any information that could identify you. Allowing your de-identified eye fluid sample to be collected and stored is optional.

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

Contact from the Jaeb Center
Separately from your research data, the Jaeb Center for Health Research will be provided with your contact information.

- After enrollment, you may receive a phone call from a staff member at the Jaeb Center to see if you have any questions. You will be called at a time that you indicate is most convenient for you. If you are not available at the time of the call and prefer to call the Jaeb Center yourself, you can call them toll-free at 1-866-372-7601

- If we are not able to locate you when we try to schedule your follow-up visit, the Jaeb Center may try to contact you through the alternative contact information you have given us. If this is not successful, the Jaeb Center may use a third-party search service.

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.

Some of your information from this study may be stored separately from or added to your medical record. You will not be able to see this information until the study ends. If your regular doctors require it for your care, they will be able to view it.

Identifiable Study Information for Future Use

Your information that is identifiable will be collected as part of the study and may be stored, maintained, or used for future research by the Jaeb Center and DRCR Retina Network. This is not the same as using the information in your regular medical records that were collected as part of your regular care outside of the study. The identifiable information that might be used include OCT scans. OCT scans are only identifiable if they can be matched to a database that already includes pictures of your retina for identification purposes. OCT scans may be made publically available. Your OCT scans could be used for other research, to help design future studies, or for teaching materials. The types of research that may be conducted with this information include analyses to help researchers better understand the condition being studied or plan future studies.

Your identifiable study information may be stored and used indefinitely.

You will not be told about the specific future uses of your identifiable study information because they are unknown at this time. This means that you will not be told about the purpose of the future research. You should think about whether there is a certain kind of research study for which you would normally not want your information to be used, because at this time we do not know what types of future studies may be done using the information collected in this study. Also, the results from the future studies will not be shared with you.

There are plans to protect your information by storing it in a secure database to which only authorized personnel have access. There are also plans to protect your information by removing any dates, names, initials, or other information from the OCT scans that could make it easier to identify you. There is still a risk 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 study information to be stored, maintained, or used for these future research purposes. You do not have to allow the Jaeb Center to store, maintain, or use your identifiable study information for future purposes if you don't want to. However, you will not be able to be in the main study if you do not agree to the future use. You will not be treated differently either way. Your regular care will not be impacted. Also, if you decide in the future that you no longer want to allow your identifiable study information to be used for future research, then you can withdraw your permission. If you decide that you want to withdraw your permission for this future use, you can contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org.

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 have had harm related to this future research process
- wish to talk about you concerns or suggestions about the storage, maintenance or use of your identifiable study information
- the future research studies

- want additional information, or
- want to provide comments

Participant's Full Name (printed) _____

Study Participation - Randomized Clinical Trial Assessing the Effects of Pneumatic Vitreolysis on Vitreomacular Traction (Protocol AG)

By signing below, you agree to take part in this study. 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 freely choose to participate and you can withdraw at any time
- you allow the future use of your identifiable study information at this time
- you will receive a copy of this consent form

_____ _____
Participant Signature Date

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You are also giving permission to allow for the storage, maintenance, and use of your protected health information for future studies. You cannot be in this study if you do not provide this permission.

_____ _____
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**

****Optional Sample Collection****

☐ **This box will be checked if your eye doctor is NOT participating in the optional sample collection component of the study (leave section below blank); otherwise continue reading and complete the section below.**

As part of this study, you have the opportunity to provide an eye fluid sample for future research. If you agree to take part in this sample collection and fluid is already being removed from the eye as part of the pre- or post-injection preparation, it will be collected and sent to a facility for future analysis. No additional procedures or risk is involved.

The sample will be stored at a facility located in the United States until the researchers are ready to analyze it. All identifiable information about you will be removed from the sample. Your sample and study data will be linked only by a code. The results from these samples will be used for research purposes only and you will not be told the results of the tests.

Sample Collection Study Enrollment

I have read the explanation above about the optional sample collection. I have been given the opportunity to discuss the study and to ask questions. I understand if I consent to provide a sample, it will be used by investigators within the DRCR Retina Network for research purposes only.

I acknowledge that I will not be contacted or asked for my consent again at the time when my sample is used.

Please choose only one of the options below:

1. ____ I hereby give my consent to have the fluid sample (if drawn as part of the study injection procedure) collected and stored for future research, or

2. ____ I **do not** want to provide the fluid sample for research use.

If you consent, you have the right to request at any time during the study that your sample be destroyed. Your sample can be destroyed (when possible) on your written request. However, if the sample has already been tested, the information obtained from the sample will not be destroyed.

Participant Signature: _____ Date: _____

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

Investigator's Signature: _____ Date: _____