UMC HEALTH SYSTEM
UNIVERSITY MEDICAL CENTER
Lubbock, Texas

Patient Label Here

DISCLOSURE AND CONSENT - MEDICAL AND SURGICAL PROCEDURES

TO THE PATIENT: You have the right as a patient to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure

1. I (we) voluntarily request Doctor(s)_____as my physician(s), and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as (lay terms)**:** Retinopathy of Prematurity (disease in the back of the eye or retina)_____

2. I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedur**e**s (lay terms)**:** Intravitreal anti-VEGF injection for the treatment of ROP (Retinopathy of Prematurity) **(SEE ATTACHMENT FOR ADDITIONAL INFORMATION)**_____

Please check appropriate box:☐ Right ☐ Left ☐ Bilateral ☐ Not Applicable

3. I (we) understand that my physician may discover other different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

4. Please initial _____**Yes**_____**No**

I consent to the use of blood and blood products as deemed necessary. I (we) understand that the following risks and hazards may occur in connection with the use of blood and blood products:

a. Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.
b. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys and immune system.
c. Severe allergic reaction, potentially fatal.

5. I (we) understand that no warranty or guarantee has been made to me as to the result or cure.

6. Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I (we) also realize that the following hazards may occur in connection with this particular procedure: Pain, severe bleeding, infection, failure of procedure, complications requiring additional treatment and/or surgery including several surgeries, recurrence or spread of the disease, infection in/or around the eye, scarring in/or around the eye, inflammation in/around the eye, persistent pain in/around the eye, corneal cloudiness, partial or total loss of vision, bleeding in/around the eye, fluid buildup inside the retina, high or low pressures in the eye, retinal detachment, anterior ischemia, loss of eye, need for further procedures **(SEE ATTACHMENT FOR ADDITIONAL RISKS & HAZARDS)**_____

7. I (we) understand that Do Not Resuscitate (DNR), Allow Natural Death (AND) and all resuscitative restrictions are suspended during the perioperative period and until the post anesthesia recovery period is complete. All resuscitative measures will be determined by the anesthesiologist until the patient is officially discharged from the post anesthesia stage of care.

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Intravitreal anti-VEGF injection (cont.)

8. I (we) authorize University Medical Center to preserve for educational and/or research purposes, or for use in grafts in living persons, or to otherwise dispose of any tissue, parts or organs removed except: None .

9. I (we) consent to the taking of still photographs, motion pictures, videotapes, or closed circuit television during this procedure.

10. I (we) give permission for a corporate medical representative to be present during my procedure on a consultative basis.

11. I (we) have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved, potential benefits, risks, or side effects, including potential problems related to recuperation and the likelihood of achieving care, treatment, and service goals. I (we) believe that I (we) have sufficient information to give this informed consent.

12. I (we) certify this form has been fully explained to me and that I (we) have read it or have had it read to me, that the blank spaces have been filled in, and that I (we) understand its contents.

If I (we) do not consent to any of the above provisions, that provision has been corrected.

I have explained the procedure/treatment, including anticipated benefits, significant risks and alternative therapies to the patient or the patient's authorized representative.

Date	Time	Printed name of provider/agent	Signature of provider/agent
_____	_____ A.M. (P.M.)	_____	_____

Date	Time
_____	_____ A.M. (P.M.)

*****Patient/Other legally responsible person signature _____ Relationship (if other than patient)

*Witness Signature _____ Printed Name

☐ UMC 602 Indiana Avenue, Lubbock, TX 79415 ☐ TTUHSC 3601 4th Street, Lubbock, TX 79430

☐ UMC Health & Wellness Hospital 11011 Slide Road, Lubbock TX

☐ OTHER Address: _____
Address (Street or P.O. Box) City, State, Zip Code

Interpretation/ODI (On Demand Interpreting) ☐ Yes ☐ No _____
Date/Time (if used)

Alternative forms of communication used ☐ Yes ☐ No _____
Printed name of interpreter Date/Time

Date procedure is being performed: _____

INTRAVITREAL ANTI-VEGF INJECTION FOR THE TREATMENT OF RETINOPATHY OF PREMATURITY

WHAT IS RETINOPATHY OF PREMATURITY (ROP)?

An eye doctor (ophthalmologist) has determined that your baby has a disease in the back of the eye or retina. The retina is a sheet of nerve cells lining the inner wall of the eye which functions like the film in a camera. Without film, a camera cannot take a picture, and without a functioning retina, the eye cannot see. When a baby is born prematurely, the retina is only partially formed. Blood vessels normally grow on the retina to provide oxygen, starting from the back of the eye at 16 weeks into the pregnancy. The growth is not complete until the end of the pregnancy. Since your baby was born early, the blood vessels have grown into the retina at the very back of the eye but not into the rest of the retina. When the growth stops, a chemical called VEGF is released that causes abnormal blood vessels to grow, leading to a condition called **retinopathy of prematurity or ROP**. ROP is a potentially blinding disease that affects several thousand premature babies each year in the United States, usually the smallest, youngest, and sickest infants.

There are several stages of ROP. In the first stage, the blood vessels stop growing and form a line that separates the normal retina with blood vessels from the premature retina without them. In the second stage, the line of separation forms a raised ridge of tissue. As the ROP advances into the third stage, abnormal blood vessels grow off of the surface of the retina toward the center of the eye. If ROP advances even more, the vessels may grow wider or dilate. This is known as "plus disease." These stages may occur in the earliest period of development when the blood vessels are still located in the back part of the retina (Zone 1) or later in the pregnancy when blood vessels have grown closer to the front edge of the retina (Zone 3). If the disease reaches a certain stage, the odds increase that the ROP will get worse. At this point, treatment is needed to reduce the likelihood of vision loss and blindness. This treatment needs to be given within three days or 72 hours.

HOW IS ROP TREATED?

Ophthalmologists usually treat ROP with **laser surgery** called **pan-retinal photocoagulation or PRP**, as long as they can clearly see the retina. PRP works by making the retina stop releasing the VEGF chemicals in the eye that cause the abnormal blood vessels to grow. Free from these harmful substances, ROP will often not get worse, the retina may remain attached, and blindness may be prevented. In the majority of babies with ROP whose eyes have been treated with PRP laser surgery, the retina remained attached and the baby did not go blind.

PRP laser surgery does not work in every baby, and not every baby can have laser surgery. Some babies are too sick to tolerate the anesthesia needed during the surgery; in others, the abnormal vessels are in an area that the laser cannot safely reach, or blood or eye structures prevent the eye surgeon from being able to see where to place the laser spots. In these situations, and in some cases of severe ROP located in the very back of the retina (Zone 1), ophthalmologists may perform **an injection with a medicine** which stops the chemicals that are harming the eye, and makes the abnormal vessels disappear. This procedure is called an **"intravitreal injection of an anti-VEGF medication (IVAV)"**. Drops are placed in the eye to dilate it and to numb it. The ophthalmologist then injects the medication into the center of the vitreous or gel that fills the eye.

HOW WILL IVAV AFFECT MY BABY'S VISION?

The goal of IVAV treatment is to stop the growth of abnormal blood vessels and prevent the retina from pulling away from the back of the eye. The treatment may need to be repeated. IVAV may not make the blood vessels disappear, or they may disappear only to come back later, sometimes after many months. Sometimes both PRP and IVAV are needed, sometimes one or the other is used alone. Sometimes one or both may need to be done more than once, depending upon how the baby's eye responds. In some cases, the ROP continues to get worse even with laser surgery and/or an intravitreal anti-VEGF injection. When this happens, the retina detaches and the eye enters stage four of ROP, and more surgery is then needed to treat ROP. **Vitrectomy surgery** uses tiny cuts into the eye to remove the vitreous jelly and release the pulling on the retina. Sometimes the lens of the eye must also be removed. Rarely, a band of silicone may need to be placed around the eye (**scleral buckling surgery**) to help the retina stay attached. Babies who have ROP develop other eye problems as they get older, such as lazy eye and crossed eye, more often than babies who were not born premature. Babies who have had ROP will need to see an ophthalmologist for lifetime eye care.

Intravitreal anti-VEGF injection (cont.)

HAS THE FOOD AND DRUG ADMINISTRATION APPROVED IVAV?

Yes. However, the Food and Drug Administration (FDA) did not approve any of these drugs to treat premature infants. Ophthalmologists have used anti-VEGF medications for many years to treat eye conditions in adults that are caused by VEGF, the same chemical that causes ROP. Avastin™ (bevacizumab) was developed and approved to stop the abnormal blood vessels that grow when colorectal cancer spreads to other parts of the body. Several medications that stop VEGF have been approved for intravitreal injections into the adult eye; these include Lucentis™ (ranibizumab), Macugen™ (pegaptanib), and Eylea™ (aflibercept). Others are used "off-label" for that purpose. Once a medication is approved by the FDA for one purpose, physicians may use it "off-label" for other purposes if they are well-informed about the medication, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects. Ophthalmologists have used Avastin™ (bevacizumab) in premature infants for a few years.

WHAT ARE THE MAJOR RISKS OF IVAV?

Risks of any procedure, surgery, or anesthesia

The eye surgeon feels that IVAV will benefit the baby. However, it is important to remember that all medications, procedures, and surgeries have both benefits and risks. The baby's condition may not get better or may become worse. Any or all of the complications described in this document may cause decreased vision and/or have a possibility of causing blindness.

Known risks of intravitreal eye injections

Possible complications and side effects of the procedure to administer the medication include but are not limited to retinal detachment, cataract formation (clouding of the lens of the eye), glaucoma (increased pressure in the eye), hypotony (decreased pressure in the eye), damage to the retina or cornea (structures of the eye), and bleeding. There is also the possibility of an eye infection (endophthalmitis). The baby may receive eye drops to reduce the possibility of this occurring. Any of these rare complications may lead to severe, permanent loss of vision in one or both eyes.

Patients may experience less severe side effects from the steps needed to prepare the eye for the injection (placement of the eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

Risks when anti-VEGF drugs are given

The first drug approved to treat VEGF conditions in the eye was Macugen™ (pegaptanib). However the greatest experience to date is with a drug initially developed to treat cancer called Avastin™ (bevacizumab). When it was given to patients whose colon cancer had spread, some patients experienced serious and sometimes life-threatening complications, such as gastrointestinal perforations or wound healing complications, hemorrhage, arterial thromboembolic events (ATE) such as stroke or heart attack, hypertension, proteinuria, and congestive heart failure. Patients who experienced these complications not only had cancer in various parts of their bodies, but were also given 400 times the dose given to treat eye conditions, at more frequent intervals, and in a way (through an intravenous infusion) that spread the drug throughout their bodies.

Risks when IVAV is used to treat adult patients with eye conditions

While there are no FDA-approved studies about the use of Avastin™ (bevacizumab) in the eye that prove it is safe and effective, three anti-VEGF drugs— Macugen™ (pegaptanib), Lucentis™ (ranibizumab), and Eylea™ (aflibercept)—have been approved for eye conditions in adults. Research on these drugs has shown that the risk of ATE events such as heart attack or stroke for adult patients with eye conditions is low. Adult patients receiving IVAV for eye conditions are healthier than the cancer patients, and receive a significantly smaller dose, delivered only to the eye. These medications have been given hundreds of thousands of times to adult patients with eye conditions without the other serious problems seen in the patients with cancer. Although there was a very low rate of ATE such as heart attack or stroke, this is a potential risk in adult patients. Patients who have diabetes may have a higher rate of death following IVAV, but the research so far cannot tell if the death is from the diabetes or the drug.

Risks when IVAV is used to treat premature infants

Ophthalmologists decided to treat ROP with IVAV based upon research begun in 2006 that is ongoing. The results so far are based upon the use of Avastin™ (bevacizumab), and show that IVAV stops the growth of abnormal blood vessels with a low risk of complications. There are some risks, however. If Avastin™ (bevacizumab) is given, the baby remains at risk for ROP to come back for a longer time. As a result, the baby will need to be seen for a longer period by the ophthalmologist to be sure that the risk of ROP has passed. Ophthalmologists have also learned that retinal detachment can still occur even if IVAV is used.

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Intravitreal anti-VEGF injection (cont.)

The eye surgeon may choose to use Lucentis™ (ranibizumab) instead of Avastin™ (bevacizumab). Anti-VEGF drugs all work very similarly, and under certain circumstances the eye surgeon may prefer one of them over another to treat ROP in your child.

The research that led ophthalmologists to use Avastin™ (bevacizumab) to treat ROP is ongoing. Ophthalmologists are still studying how well IVAV works to treat ROP and how safe it is, as well as the best amount to give, how often it should be given, and what types of ROP respond best. Premature babies need VEGF for their lungs, brains, and kidneys to develop. A small amount of the medication that is injected into the eye leaves the eye and enters the baby's bloodstream. It is not yet known if this amount in the bloodstream may prevent the baby's lungs, brains, and kidneys from developing completely or cause some harm. Results so far indicate that it does not. **It is too soon to know if there are long-term effects of IVAV in premature infants that could cause problems in the eye or other body parts.**

It is also hard to know if problems that do show up are the result of the IVAV. Premature infants have many other conditions caused by being born too soon. These other conditions can also cause injury on their own and may make injury or complications from ROP treatment more likely to happen or harder to treat. The ophthalmologist will talk to the baby's doctor when deciding whether to give IVAV.

DOES MY BABY HAVE TO HAVE TREATMENT FOR ROP?
Without one or more of these treatments, your baby could end up with very poor vision or blindness in both eyes. As an adult, you have the legal right to refuse treatment to save your own vision or life. Babies cannot make these decisions, of course. While you have the legal right to make decisions for your baby, the doctor has a legal duty to provide medical care to the baby. If you refuse treatment that a doctor decides is needed to prevent harm to your baby, your doctor is required to ask other doctors and child protective services to talk to you about your decision.

CARETAKER'S ACCEPTANCE OF RISKS
I understand that it is impossible for the doctor to inform me of every possible complication that may occur. By signing below, I agree that the doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of intravitreal injection of the anti-VEGF medication called: _____ (state name of drug) in my baby's: ☐ Right ☐ Left ☐ Bilateral eye(s).

I understand that it is my right to refuse this treatment for my baby. I also understand that if I do refuse the treatment, then the doctor must ask other doctors or child protective services to talk to me about my decision.

_____ _____A.M. (P.M.)
Date Time

_____
*****Patient/Other legally responsible person signature Relationship (if other than patient)

_____
*Witness Signature Printed Name

☐ UMC 602 Indiana Avenue, Lubbock, TX 79415 ☐TTUHSC 3601 4th Street, Lubbock, TX 79430
☐ UMC Health & Wellness Hospital 11011 Slide Road, Lubbock TX
☐ OTHER Address: _____
Address (Street or P.O. Box) City, State, Zip Code

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Resident and Nurse Consent/Orders Checklist

Instructions for form completion

Note: Enter "not applicable" or "none" in spaces as appropriate. Consent may not contain blanks.

Section 1: Enter name of physician(s) responsible for procedure and patient's condition in lay terminology. Specific location of procedure must be indicated (e.g. right hand, left inguinal hernia) & **may not be abbreviated.**

Section 2: Enter name of procedure(s) to be done. Use lay terminology.

Section 3: The scope and complexity of conditions discovered in the operating room requiring additional surgical procedures should be specific to diagnosis.

Section 5: Enter risks as discussed with patient.

A. Risks for procedures on List A must be included. Other risks may be added by the Physician.
B. Procedures on List B or not addressed by the Texas Medical Disclosure panel do not require that specific risks be discussed with the patient. For these procedures, risks may be enumerated or the phrase: "As discussed with patient" entered.

Section 8: Enter any exceptions to disposal of tissue or state "none".

Section 9: An additional permit with patient's consent for release is required when a patient may be identified in photographs or on video.

Provider Attestation: Enter date, time, printed name and signature of provider/agent.

Patient Signature: Enter date and time patient or responsible person signed consent.

Witness Signature: Enter signature, printed name and address of competent adult who witnessed the patient or authorized person's signature

Performed Date: Enter date procedure is being performed. In the event the procedure is NOT performed on the date indicated, staff must cross out, correct the date and initial.

If the patient does **not** consent to a specific provision of the consent, the consent should be rewritten to reflect the procedure that the patient (authorized person) is consenting to have performed.

For additional information on informed consent policies, refer to policy SPP PC-17.

Consent

☐ Name of the procedure (lay term)	☐ Right or left indicated when applicable
☐ No blanks left on consent	☐ No medical abbreviations

Orders

☐ Procedure Date	☐ Procedure
☐ Diagnosis	☐ Signed by Physician & Name stamped

Nurse_____Resident_____Department _____

THIS FORM IS NOT PART OF THE MEDICAL RECORD