NOTE:  THIS FORM IS INTENDED AS A SAMPLE FORM. IT CONTAINS THE INFORMATION OMIC RECOMMENDS YOU AS THE SURGEON PERSONALLY DISCUSS WITH THE PATIENT. PLEASE REVIEW IT AND MODIFY TO FIT YOUR ACTUAL PRACTICE. GIVE THE PATIENT A COPY AND SEND THIS FORM TO THE HOSPITAL OR SURGERY CENTER AS VERIFICATION THAT YOU HAVE OBTAINED INFORMED CONSENT.

**INFORMED CONSENT FOR OPEN GLOBE INJURY (OGI) INITIAL REPAIR**

**(Repair of cut to or rupture of the eyeball)**

**WHY MIGHT I NEED REPAIR OF THE INJURY TO MY EYE?**

The cornea is the clear front window of the eye and the sclera is the white part of the eye. A laceration is an injury, like a cut, partially or fully through the cornea or sclera (the eyeball). Rupture of the eyeball can be caused by significant blunt force to the eyeball, such a sports ball or fist hitting the eye, or a sharp object. Full-thickness lacerations and ruptures are known as open globe injuries (OGIs). Without repair of the wound, there is a high chance of infection, severe or total loss of vision, and cosmetic disfigurement. Many OGIs result in the contents of the eye (iris, lens, vitreous gel, and retina) being pushed out of the eye. If not replaced into the eye or excised, the wound cannot heal and function is lost. In some cases of lacerations, a foreign body may enter and remain in the eye. If not removed, foreign bodies can harbor infection, damage the inside of the eye by moving around, and release substances toxic to the eye. Eye injuries can be associated with injuries to the surrounding eye muscles, bony structures around the eyewall, the nerve responsible for vision (the optic nerve), and facial structures. Other major consequences and risks of OGI include:

* Infection, which can lead to severe damage inside the eye and total loss of vision and of the eye
* Bleeding inside the eye, which can cause permanent vision loss and may require surgery
* Loss of ocular contents (iris, lens, vitreous gel, and retina), which can be pushed out of the eye by the initial trauma or, after the initial trauma, by lid squeezing or eye rubbing
* Loss of portions of the eye (cornea and sclera), which may require grafts or removal of the eyeball
* Retinal tears and detachment, which may require laser treatments or additional surgery, or may be too severe to repair, leading to permanent loss of vision
* Retinal swelling (cystoid macular edema), which may require eye drops or injections
* Glaucoma (elevated pressure inside the eye, which may lead to loss of vision by damaging the optic nerve (the nerve responsible for eyesight), and which may require eye drops, laser treatment, or surgery
* Poorly healing or non-healing wounds, which may require additional surgery
* Corneal clouding and scarring, which may require additional surgery
* Cataract (clouding of the natural lens), which may require immediate or eventual removal of the lens
* Double vision, which may require prism glasses or eye muscle surgery
* Eyelid cosmetic deformity, such as a droopy eyelid, which may require surgery
* Loss of blood circulation to vital tissues in the eye, which may result in a decrease or loss of vision
* Damage to the optic nerve (the nerve responsible for vision) with loss of vision
* Phthisis (disfigurement and shrinkage of eyeball) which may require a cosmetic contact lens or removal of the eyeball if painful and can lead to asymmetry/cosmetic deformity

For some patients, the traumatic episode, changes in vision and appearance, and the often prolonged course of medical management may lead to anger, anxiety, depression, or other normal but severe emotional reactions. If these occur, it is important to seek treatment, reach out for support, and develop coping skills. Additionally, it is very important to assure protection and routine evaluations of the non-injured eye.

Initial surgical repair is intended to prevent further damage to the eye, prevent infection, and provide the best chance at restoring vision and cosmetic appearance.

**HOW IS THE INITIAL OPEN GLOBE INJURY (OGI) REPAIR (SURGERY) DONE?**

Initial OGI repair is performed in an operating room under anesthesia.

If there is hope of improving or restoring vision and maintaining cosmetic appearance, the surgeon will attempt to close the laceration/rupture at the initial OGI repair. Stitches will be placed to close the eyeball (restore its integrity). Your doctor will choose the best type of stitches for your specific wound and depending on the type used, they will be removed later or may dissolve on their own. Foreign bodies may be removed at the time of initial surgery, especially if protruding from the eye. In some situations, in which it is not safe to remove foreign bodies at the initial OGI repair, foreign bodies may be left for removal at a later date by a retina surgeon. Ocular contents that have been pushed out from inside the eye may be put back into the eye or removed, depending on the circumstances.

In rare cases where the eye is damaged beyond repair and there is no chance of saving any vision, your doctor will remove the hopelessly damaged eyeball, instead of trying to repair it, to prevent or reduce the risk of infection, cosmetic disfigurement, chronic pain, or a very rare condition in which inflammation attacks the non-injured eye.

Severe injuries may require more than one operation to restore vision and improve cosmetic appearance. Initial OGI repair may be the first of many steps in a series of medical and surgical interventions to restore structure and function. Even with multiple surgeries, severe injuries can result in vision loss and cosmetic deformity.

**HOW WILL THE INITIAL OPEN GLOBE INJURY (OGI) REPAIR AFFECT MY VISION OR APPEARANCE?**

The results of the initial repair of the OGI depend upon the severity and location of the injuries. Initial OGI repair is intended to restore the integrity of the eyeball, prevent infection, prevent further injury, and, in doing so, maximize the chances of eventual visual and cosmetic improvement. Initial OGI repair may or may not by itself improve vision or cosmetic appearance.

**Some patients have unrealistic expectations about how open globe injury repair will impact their lives. Even in the hands of the best surgeons, some injuries are so severe and extensive that vision may be permanently impaired or even completely lost and the injured eye may eventually need to be removed.** You should carefully understand the severity of the injury, the risks of the repair, and ask questions before agreeing to surgery.

**WHAT ARE THE MAJOR RISKS OF THE INITIAL REPAIR (SURGERY) FOR OPEN GLOBE INJURY (OGI)?**

The intent of initial repair of the OGI is to restore the integrity (seal the open defect) of the eyeball to prevent infection and maximize visual and cosmetic recovery. The full extent of damage to the eye and surrounding structures may not be apparent before and during initial OGI repair. Damage from the initial trauma, even if it only becomes apparent after initial OGI repair, is not a complication of the initial surgery.

Risks of initial OGI repair include all the consequences of the OGI (listed above in the section **WHY MIGHT I NEED REPAIR OF THE INJURY TO MY EYE?**) and, in particular, bleeding, infection, permanent vision loss, inflammation of the uninjured eye, and loss of the eye. Due to individual differences in severity of injury and variable wound healing, no guarantees can be made as to your final result.

**WHAT ARE THE ALTERNATIVES?**

The alternatives are to not have surgery or to delay surgery. If you delay or do NOT have surgery to close the OGI, you have a much higher risk, and in some situations are guaranteed, to lose some or all vision permanently and/or to suffer from permanent cosmetic deformity. Ideally, initial surgical repair is performed soon after the injury to minimize the risk of further damage and infection.

**WHAT TYPE OF ANESTHESIA IS USED? WHAT ARE THE MAJOR RISKS?**

Most eyeball trauma repair surgeries are performed under anesthesia with you partially or completely asleep. Risks of anesthesia include but are not limited to damage to the eye and surrounding tissue and structures (from the numbing shots), loss of vision, infection, damage to mouth and/or breathing structures, breathing problems, and, in extremely rare circumstances, stroke or death. The anesthesiologist will review the specific risks of the type of anesthesia you will have with surgery.

**PATIENT’S ACCEPTANCE OF RISKS**

By signing below, you agree that:

* You have read (or someone read to you) the above information and you have discussed it with your doctor
* Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has answered all of your surgical questions and has encouraged you to ask any questions prior to surgery
* It is impossible for your doctor to inform you of every possible complication that may occur with the initial open globe injury repair
* Your doctor has told you that results cannot be guaranteed, and that adjustments and/or more surgery may be necessary
* You understand the risks, benefits, and alternatives to open globe injury repair
* You feel able to accept the risks involved

I consent to open globe injury repair surgery on my (write “right”, “left”, or “both”) eye/eyes:

**X**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient (or person authorized to sign for patient) Date and time

**Physician Declaration:**  The contents of this document have been explained to the patient and all questions and concerns have been answered. To the best of my knowledge, I feel that the patient has been adequately informed and has consented.

**X**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Date and time

Addendum

**INFORMED CONSENT FOR SURGERY TO DETERMINE IF THERE IS AND OPEN GLOBE INJURY (OGI) AND TO PERFORM INITIAL REPAIR OF A CUT TO OR RUPTURE OF THE EYEBALL**

**WHY MIGHT I NEED SURGERY (EYEBALL EXPLORATION) TO DETERMINE THE EXTENT OF THE INJURY TO MY EYE?**

The cornea is the clear front window of the eye and the sclera is the white part of the eye. A laceration is a cut, usually caused by a sharp object such as glass or metal, partially or fully through the cornea or sclera (the eyeball). Rupture of the eyeball can be caused by significant blunt force to the eyeball, such as a sports ball or fist hitting the eye. Full-thickness lacerations and ruptures are known as open globe injuries (OGIs). Without repair of the wound, there is a high chance of infection, severe or total loss of vision, and cosmetic disfigurement.

Your doctors have used all available means (e.g. physical examination) to determine if you have an OGI, but have been unable to exclude the possibility that you have an OGI. There is enough of a chance that you may have an OGI that your doctor recommends that you have a surgical exploration of the surface of the eyeball in the operating room. This will require opening the tissue around the eye to allow examination of the back portion of the eyeball.

**HOW IS THE EYEBALL EXPLORATION DONE?**

Eyeball exploration to look for an open globe injury (OGI) is performed in an operating room under anesthesia. The surgeon will surgically open the soft tissue around the eye to expose and visually inspect the back parts of the eyeball. If an OGI is found, your physician will proceed to **INITIAL OPEN GLOBE INJURY (OGI) REPAIR (SURGERY)** to prevent further damage to the eye, prevent infection, and provide the best chance at restoring vision and cosmetic appearance.