**THIS IS A SAMPLE CONSENT FORM. Review and revise as needed.**

**Remove this section.**

**Add your letterhead to the first page of the consent form.**

**Keep each section together on the same page: move it as needed.**

**Change font size for large print.**

**Version 3/12/20**

ILUVIEN (fluocinolone acetonide implant)

You have diabetic macular edema (DME). This means that diabetes has damaged the back of your eye (macula) and caused swelling (edema). DME may cause poor vision and vision loss. Your ophthalmologist (eye surgeon) recommends treatment with an implant called ILUVIEN. The implant is a tiny tube that contains a steroid.

**The ILUVIEN implant is placed in the back of your eye by an injection (shot).** The eye surgeon begins by putting in eye drops to dilate (enlarge) the pupil (black circle) in the center of your eye so he or she can see the back of your eye clearly. Next, the eye surgeon numbs the eye so that you do not feel any pain. Then the eye surgeon injects the ILUVIEN implant into the back part of your eye. The implant stays in your eye and slowly releases the steroid for up to 3 years.

**You may have some minor problems right after the injection.**

* Your vision might be blurry right after the injection. Do not drive or use machines until your vision gets better.
* Your eye may be irritated and make a lot of tears for a few hours.
* The white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye. It will not change how well you see. This will clear up in a few days or a week.
* You might see small specks called floaters. Many people already have floaters. These new floaters may go away in a few days, or you may stop noticing them.

**Tell the ophthalmologist right away if you notice any other problems after the injection such as:**

* Eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, and pus or other discharge coming from the eye.
* New or large floaters that do not go away.
* Flashing lights or decreased side vision with the floaters.

You can help prevent or reduce these problems. Do not rub your eyes or go swimming for 3 days after each injection. Call your ophthalmologist right away if you notice any of these problems. Keep all appointments with your ophthalmologist.

**Benefits (how this medication can help).** The goal of using ILUVIEN is to reduce the swelling, stop the damage, and prevent more vision loss. But ILUVIEN may not restore (bring back) vision loss that happened before treatment.

**Alternatives (choices and options).** ILUVIEN is not the only option. Your other treatment choices may include:

* No treatment. If you decide not to have treatment, then your eye problems can get worse, and cause further vision loss or even blindness.
* Other medications used by eye surgeons to treat diabetic macular edema. Talk with your eye surgeon about the risks and benefits of these medications.
* Laser surgery to treat leaking blood vessels in the eye that might be causing the swelling.

**Risks (problems this medication may cause).** There are risks with the medication, the injection, and the implant. While your eye surgeon cannot tell you about every risk, here are some of the most common or serious ones:

* Risks from steroids
  + Cataract (clouding of the eye’s lens) leading to the need for cataract surgery
  + High eye pressure, leading to optic nerve damage and glaucoma, and the need for eye drops or glaucoma surgery
  + Hypotony (reduced eye pressure)
  + An eye infection that could cause vision loss or blindness
  + Thinning of the cornea (clear front of the eye) or sclera (white part of the eye, leading to rupture of the globe that holds the eye in place
* Risks from the injection
  + An eye infection that could cause vision loss or blindness
  + Inflammation inside the eye that can cause vision loss, pain, or redness
  + Increase or decrease in eye pressure
  + Detached retina (the light-sensitive part of the back of your eye might get pulled off)
  + Retina or cornea damage
  + Bleeding within the eye
* Risks from the implant
  + The implant could move from the back of your eye into the front of your eye
  + You may need surgery to remove or reposition the implant
  + The implant does not dissolve
* ILUVIEN might not improve your vision. It could make your vision worse.
* Eye problems from the ILUVIEN implant can appear days, weeks, months, or even years after your injection. The costs to treat these are not included in the fee you pay for the ILUVIEN implant.

**By signing below, you consent (agree) that:**

* You read this informed consent form or had it read to you.
* You have been offered a copy of this consent form.
* You were told you have diabetic macular edema.
* Your questions about ILUVIEN have been answered.
* You consent to having the eye surgeon inject ILUVIEN into your \_\_\_\_\_\_\_\_ (“right,” “left,” or “both”) eye.

Patient (or person authorized to sign for patient) Date