**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 3/13/20**

**YUTIQ (fluocinolone acetate) Implant**

You have an eye condition called chronic non-infectious posterior uveitis. This means that the back of your eye has inflammation that can last a long time, and is not caused by an infection (such as a virus or bacteria). Uveitis may cause eye redness, pain, blurry vision, and vision loss. Your ophthalmologist (eye surgeon) recommends treatment with an implant called YUTIQ. The implant is a tiny tube that contains a steroid to help control the inflammation.

**The YUTIQ implant is placed in the back of your eye by an injection (shot).** The ophthalmologist may put eye drops to enlarge the pupil (black circle) in the center of your eye to see the back of your eye clearly. Next, the ophthalmologist will numb your eye as much as possible so that you do not feel any pain. Then the ophthalmologist injects the implant. The implant will stay in your eye and slowly release the YUTIQ medication 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 YUTIQ for eye problems is to control the inflammation caused by uveitis and help you keep the vision you have. YUTIQ might not restore (bring back) vision you have already lost.

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

* No treatment. If you decide not to have treatment when the uveitis is active, then your uveitis could get worse. You could have more vision loss or even blindness.
* Other medications approved by the Food and Drug Administration (FDA) for treating your type of eye problem.
* Other medications approved by the FDA for a different condition. Ophthalmologists use these medications “off-label” because they can help lessen inflammation and swelling that decreases vision.
* Your ophthalmologist will tell you about the risks and benefits of these medications

**Risks (problems this medication may cause).** There are risks with the medication, the injection, and the implant. These risks can cause vision loss or blindness. YUTIQ contains a steroid. While your ophthalmologist cannot tell you about every risk, here are some of the most common and 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
* YUTIQ might not improve your vision. It could make your vision worse.
* Eye problems from YUTIQ 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 YUTIQ injection.

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

* You read this informed consent form or had it read to you.
* You were told you have chronic posterior uveitis.
* Your questions about using YUTIQ to treat this eye problem were answered.
* You consent to have the ophthalmologist inject YUTIQ into your \_\_\_\_\_\_\_\_\_\_\_ (“right,” “left”, or “both”) eye(s).

Patient name Date