# Ophthalmology ICF Template Language Recommended by The Eye Institute

Note: This is not an exhaustive list and sometimes sponsors call exams by various names. It is always best to check with your Eye Institute contact regarding what should or should not be included in the ICF for your specific project

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 **B1. WHAT WILL HAPPEN IF I PARTICIPATE?**

INSTRUCTIONS

* **Blue text** is “standard” language recommended by the Eye Institute.
* **Green text** is variable and may be included/removed based on protocol requirements.
* **Black text** includes notes and references regarding procedures or other common names for procedures and should be deleted.
* **Vision Tests:**

You will be asked to read different sized letters off a chart to test your vision (visual acuity). For this test, you will be asked to wear special glasses while different lenses are presented to you. We will test your visual acuity while you are wearing the lenses that allow you to read the most clearly.

* **Schirmer’s Test:**

A strip of thin paper will be placed inside your lower eyelid to measure the amount of tears that your eyes produce.

* **Pupil Dilation:**

We may put drops in your eyes to dilate (or widen) your pupils. If you may be pregnant or are nursing a baby you will not be dilated, since the effects of the dilating drops on an unborn or nursing baby are not known.

* **Eye Exam:**

A doctor may check your eyes using a low-powered microscope with a bright light and magnifying lenses. As part of the eye exam, we may measure your intraocular pressure (the pressure inside your eye). To check your intraocular pressure, you will be given a numbing eye drop and then a special instrument will touch your eye for a few seconds to take a measurement.

The doctor may also apply colored stains or dyes to the front of the eye to check for abnormalities of the surface layer of the eye (conjunctiva). The colored stain may be applied as a drop or using a sterile paper applicator dampened with eye wash or a numbing drop. If you have had a recent eye exam, we may be able to use information from your medical record instead of completing an eye exam during your study visit.

* **Slit Lamp Photography:**

For this testing you will sit at a slit lamp, similar to what an eye doctor uses for an eye exam. We will use a camera attached to the slit lamp to take pictures of the structures at the front of your eye. The light used to help take these pictures may be bright.

* **Fluorescein Angiography:**A dye called fluorescein will be injected into a vein for this test. Then, images will be taken of the back of your eye as the dye moves through the blood vessels in the back of your eye. If you are allergic to fluorescein dye, please let the study team know.
* **Pachymetry:**After numbing the front of your eye with an eye drop, we will touch a small probe to the surface of the eye in several different places. This probe will measure the thickness of the front of your eye, or cornea
* **Visual Field Testing:**This testing shows which areas of the back of your eye are the most sensitive to light. You will be shown dots of light in different areas of your vision and will be asked to press a button each time you see a light.
* **Optical Coherence Tomography (OCT):**

These images show us how thick your retina is and can also allow us to study different layers of the retina (including blood vessels). You may see some moving or flashing lights while the images are taken.

* **Fundus Photography:**

We will take images of the top layer of the retina so that we can see the blood vessels and other larger structural features. The devices used to take these images use different types of light.

**C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?**

* **Schirmer’s Test:**There is a small chance that the filter paper placed on the surface of the eye could scratch the top layer of the eye (the cornea).
* **Pupil Dilation:** Dilating drops may sting temporarily when they are placed in your eyes. While your eyes are dilated, you will likely experience blurred vision, difficulty focusing, and sensitivity to light. You may also experience a headache or watering of the eyes. The effect of the dilating drops lasts several hours. Very rarely (less than 1% of the time), you may have redness, discomfort, or an allergic reaction to the drops that are used to dilate the pupil. This is generally not serious and can be treated if it occurs. Some types of glaucoma (i.e. angle-closure glaucoma) may be made worse by dilating drops in some people, but this can also be treated.
* **Eye Exam:** The lights used by the doctor for the eye exam are bright and may be uncomfortable, but they are not expected to harm your eyes. Intraocular pressure testing can rarely cause minor scratching to the front of the eye. Since you will be given numbing drops before this test, it is important to avoid rubbing your eyes for at least fifteen minutes after receiving the drops, since small particles or dust could scratch the front of your eye without you noticing any pain.

Colored stains used for the exam may cause mild irritation and may cause your eye to look discolored temporarily. If you wear contact lenses and put them in while the stain is still present, the stain may discolor your contact lens.

* **Fundus Photography** Some of the light used to take these images may be very bright. These bright lights may cause temporary discomfort but will not harm your eyes.
* **Pachymetry:**There is a small chance that the probe placed on the surface of the eye could scratch the top layer of the eye (the cornea)
* **Slit Lamp Photography:** The light used to take these images may be bright. This may cause temporary discomfort but will not harm your eyes.
* **Fluorescein Angiography**: The fluorescein dye injected into your arm or hand may turn your skin yellow for a few hours. The dye will also turn your urine a bright yellow-orange color, which is normal and may take up to two days to go away. You may feel uncomfortable when the dye is injected into your vein. You may have a reaction to the dye. This could be mild (lightheadedness, dizziness, nausea, vomiting, rash) or serious (trouble breathing). The study team will watch for any signs of side effects and will give you anti-allergy medication if needed. If you know you have an allergy to fluorescein, let the study team know and we will not do this testing.

The following procedures do not have any known risks:

* Vision tests
* OCT
* Visual Field Testing