

Informed Consent for Off-Label use of a Drug or Device

This form is intended as a sample. It does not constitute the standard of care nor does it provide legal advice. It contains the information OMIC recommends the surgeon personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your actual practice.
* **Remove this instruction box.**
* Add your letterhead to the first page of the consent form.
* Change font size if necessary.

**After the patient signs the form**

* Give the patient a copy of the signed form.
* Send a copy to the hospital or surgery center as verification that you have obtained informed consent.
* Keep the original in the patient’s medical record.

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SAMPLE CONSENT DOCUMENT TEMPLATE FOR DRUG OR DEVICE

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a “label” to explain its use. Once a device/medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

[State purpose of the off-label drug/device.]

[State alternatives to the off-label drug or device.]

[State known complications and side effects of the off-label drug/device.]

I understand that [state drug/device] was approved by the FDA for [state approval purpose/conditions]. Nevertheless, I wish to have [state treatment/procedure] performed on my eye/used in my eye and I am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of [state drug/device] are not known.

If the complication happens during surgery, your surgeon may need to perform another surgery right away to treat it. Your surgeon may discover a new condition or problem for the first time during the surgery. The surgeon may need to change the plan for surgery to treat this problem or condition right away.

PATIENT’S ACCEPTANCE OF RISKS

Your signature on this document means:

* You have read it (or it has been read to you) and you understand this information.
* You have been offered a copy of this document.
* Your doctor has answered your questions to your satisfaction.
* You consent to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (procedure) on your \_\_\_\_\_\_\_\_\_\_\_\_ eye (state “left”, “right”, or “both eyes”).

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Patient (or person authorized to sign for patient) Date