Informed consent for off-label use of a drug or device

DISCLAIMER: This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.

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.