Informed Consent

"Off-Label" Use of XXXXX

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INSTRUCTIONS

This document is about informed consent. It will explain the off-label use of **xxxx.**

It is important that you read this whole document carefully. Please read this and sign the consent for surgery as discussed with your plastic surgeon.

GENERAL INFORMATION

The Food and Drug Administration (FDA) mandates medical devices to be safe and effective. A device's label says it may only be used in certain ways. These are to treat a specific condition.

"Off-label" use is when a device is used to treat a condition not approved by the FDA. Sometimes, doctors may use a device in off-label ways. This is based on their training and experience.

XXXXX

In order to **xxxxx**, your physician may opt to use **xxxxx**. Often, these **xxxxx**

_____ **Patient Initials**
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This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form or any modified version of this form, meets the requirements to obtain informed consent for this procedure in the jurisdiction of your practice.

CONSENT FOR SURGERY/PROCEDURE

1. I am aware that **xxxx** has received FDA approval for certain uses. This is an "off-label" and non-approved use for **xxxxx** surgery.
2. I understand the details of this treatment. I know about the benefits and risks.
3. I am aware that there may be other treatments and that they have their own benefits and risks.
4. I understand the most common risks of using **xxxxx** for off-label use, like
   - Seroma
   - Site infection
   - Wound opening
   - Hematoma
   - Skin necrosis
5. I have told my doctor of all known allergies.
6. I have told my doctor of all current medications. This includes prescription and over-the-counter drugs, herbal therapies and supplements, aspirin, and any kind of drug or alcohol use.
7. My doctor has told me what medication I should and should not take after use of **xxxxx.**
8. I am aware that there are no guarantees as to the results of **xxxxx**.
9. The doctor has answered all my questions about **xxxxx.**

I have read and understood this agreement.
I permit Dr. Steve Sample to prescribe_____for_____, which is an "off-label" and non-approved use.

I CONSENT TO THE TREATMENT AND THE ITEMS LISTED ABOVE (1-9).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____

Patient or Person Authorized to Sign for Patient Date/Time

Witness_____Date/Time_____

I have explained the nature, purpose, benefits, risks, problems, and options of the proposed surgery/treatment to the patient or the patient's legal representative. I have encouraged the patient/legal representative (circle one) to ask questions and have answered all their questions.

_____

Physician Signature/Date/Time

_____**Patient Initials**

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