OFF-LABEL USE OF [Name of Device]

Since the early 1960s, the Food and Drug Administration (FDA) has required that medical devices, including electronic radiation-emitting products, used in the United States be both safe and effective. The label information on the device and in any advertising may indicate a device's use only in certain ways that are "approved" for a particular condition. The use of a device for a condition not listed on the label or in a dose different from that specified on the label is considered to be a "nonapproved" or "off-label" use of the device. Physicians—based on their knowledge, education, training, experience, and available current information—may use a device for a use not indicated on the "approved" labeling if it seems reasonable or appropriate in the physician's professional judgment.

Patient's Initials

_____ I understand that this is an experimental use of this device, therefore no one can be fully aware of all possible side effects and complications.

_____ The details of this treatment, including the anticipated benefits, material risks, and disadvantages, have been explained to me in terms I understand.

_____ Alternative treatments, prescriptions, and therapies, and their benefits, material risks, and disadvantages have been explained to me in terms I understand.

_____ I understand and accept that the most likely material risks and complications of using [Name of Device] for off-label use have been discussed with me and may include but are not limited to:

- •
- •
- •
- •

_____ I have informed the doctor of all my known allergies.

_____ I have informed the doctor of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies and supplements, aspirin, and of any recreational drug or alcohol use.

_____ I have been advised whether I should avoid taking any or all of these medications while I am using the above device.

_____ I am aware and accept that no guarantees about the results of this device have been made.

_____ The doctor has answered all of my questions regarding this device.

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

I authorize and direct _____, MD/DO, to prescribe _____,
(name of device)

which is FDA-approved for the treatment of _____,
(*condition device was approved to treat)*

for the purpose of _____.
(condition to be treated)

_____ _____
Patient or Legal Representative Signature/Date/Time *Relationship to Patient*

_____ _____
Print Patient or Legal Representative Name *Witness Signature/Date/Time*

I certify that I have explained the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed therapy to the patient or the patient's legal representative. I have answered all questions fully, and I believe that the ***patient/legal representative*** *(circle one)* fully understands what I have explained.

_____
Physician Signature/Date/Time

_____ copy given to patient
initial

_____ original placed in chart
initial