Consent form for off-label use of Pulmicort (Budesonide) Respules

I understand and agree to the off-label use of a specific medication – Pulmicort Respules - in the management of my sinus condition. I understand that Off-label prescribing, also known as unapproved use, is the physician practice of prescribing a drug for a purpose different from one of the indications for which the product is approved by the Food and Drug Administration (FDA). Because there has not been sufficient testing by the FDA, my physician does not have tested information on use, dosage, and route of administration that is provided in product labeling for approved indications. Furthermore, the safety and efficacy of the unapproved use has not have been established by adequate and well-controlled clinical trials. Risks include, but are not limited to stuffy nose, sore nose, runny nose, cough, viral infections, stomach upset, ear infections, nosebleeds, conjunctivitis (pink eye), rash. Other risks include disruption of the Hypothalamic-Pituitary Axis, adrenal gland disruption and suppression, increased eye pressure, cataracts and other eye and vision problems, increase in blood sugar, avascular necrosis, increased risk of infections, gastro-intestinal ulcers/nausea/vomiting, insomnia, muscle atrophy/joint pain. Since this is an off-label usage of this medication, I understand that there are other risks which may be unknown or unlisted here. I also understand that I have other alternatives – medical and surgical – to this off-label use. With this knowledge of the potential risks, benefits, alternatives, and complications, I request that my doctor proceed with the off-label prescription of Pulmicort respules. I also acknowledge that the doctor has reviewed the use of this medication with me in detail, and answered all of my questions on the subject of the use of this medication. I confirm that I have been given a copy of this form, which is also posted on the web site – www.noseandsinus.com

Patient name (printed) Date Patient signature

_____ _____ _____

I confirm that I have reviewed in detail the reasons for my recommendation of the off-label prescription of Pulmicort respules for this patient. I have reviewed with the patient the meaning of "off-label" prescription of medication, and discussed at length the risks and potential complications – known and unknown – to this usage. I have also reviewed in detail the alternatives to this usage of Pulmicort respules. I affirm that that patient expresses understanding of these risks, benefits, alternatives, and complications and would like to proceed with off-label usage of Pulmicort respules.

Physician name (printed) Date Physician signature

_____ _____ _____