

IRB# _____
Approved: _____

OREGON HEALTH & SCIENCE UNIVERSITY
Humanitarian Use Device Consent Form for Treatment Only

TITLE: HDE# [Give number assigned by FDA]: [Give name of device]

PHYSICIAN: Name, Degrees (503)-494-XXXX

TREATMENT TEAM: Name, Degrees (503)-494-XXXX
Name, Degrees (503)-494-XXXX

INTRODUCTION:

Your doctor has told you that you have [give diagnosis and lay definition]. Your doctor thinks that it would be best to treat this disorder with [give name of device]. The Food and Drug Administration (FDA) has approved this device for treating this problem.

PROCEDURES:

Explain procedures even if standard of care in lay language in chronological order.

RISKS AND DISCOMFORTS:

Explain the risks of the device and the procedures, even if the procedures are standard of care, in lay language. You may wish to refer to OHSU's standard research consent template for wording to describe the risks of some common procedures.

ALTERNATIVES:

Other treatments for your condition include [give standard approved options. If there are none, so state. If some of the options are experimental, you may refer to them, but clearly inform the subject that their effectiveness is unproven.].

CONFIDENTIALITY:

All of the records related to your treatment will be placed in your medical record as usual. If there is a problem with your treatment (such as a side effect or device failure), your doctor is required to report the problem to the Institutional Review Board at the Oregon Health & Sciences University. They may review and copy the parts of your medical record related to your

treatment with this device. No one else will be allowed to see your medical records without your permission.

COSTS:

Your insurance company will be billed for the cost of your treatment with this device. If your insurance will not pay, you will be billed.

QUESTIONS:

[*Name, phone number*] has offered to answer any other questions you may have about this treatment. Your signature below shows that you have read this form and agree to this treatment.

Patient's signature

Date