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| **CONSENT TO UNDERGO TREATMENT WITH A** | |
| **HUMANTARIAN DEVICE** | |
| UNIVERSITY OF CALIFORNIA, IRVINE INSTITUTIONAL REVIEW BOARD | |
| Name of Treating Physician, Physician’s Telephone Number(s)  [List a 24 hour number here]  Physician’s Department(s) | |
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| NAME OF PATIENT: |  |
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| A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals per year in the United States and for which no comparable device is available. The U.S. Food and Drug Administration (FDA) approves the use of a Humanitarian Use Device based primarily on evidence that it does not pose an unreasonable or significant risk of illness or injury to the patient and that the probable benefits to health outweigh the risk of injury or illness from its use; however, the effectiveness of the device for [name of disease or condition] has not been demonstrated. The use of the HUD is approved for your condition by the FDA. The use of the HUD does not involve research.  **Patient’s Condition:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Name of Device:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **PURPOSE OF THE HUMANITARIAN USE DEVICE**  Describe the specific indication for use of the HUD.  **PROCEDURES INVOLVED WITH THE USE OF THE HUMANITARIAN USE DEVICE**  Describe the procedures chronologically; include the placement of the device.  **POTENTIAL RISKS OF TREATMENT**  The possible risks and/or discomforts associated with the procedures described and the use of the device include:  [Using simple, short sentence, describe the risks involved with the placement and use of the device. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted.]  **POTENTIAL BENEFITS ASSOCIATED WITH TREATMENT**  The possible benefits you may experience from the use of the device include:  [Describe the potential benefits of use of this device, with particular reference to the patient’s disease or condition.]  **ALTERNATIVE TREATMENT OPTIONS**  If you do not agree to this treatment or if the treatment is stopped early, the following alternatives are available to you:  [Describe the therapeutic alternatives available to the patient]  **PATIENT COSTS**  You or your insurance provider will be responsible for all cost associated with the procedures and use of the [device name].You will also be responsible for all costs related to the treatment of your [name of disease or condition]. Your physician will discuss the costs of this procedure with you.  **PATIENT CONSENT**  The placement and procedures involved in the use of the Humanitarian Device has been fully explained to me and I have been told that any questions I have will be answered at any time by the doctor. I have also been informed that this device has been approved for my condition by the FDA and I am not a subject in a research study.  I have read a copy of the attached Patients’ Bill of Rights and have been given a copy of it and this consent form to keep. I have had a chance to ask any questions I have about the device and procedures. I consent to receiving the Humanitarian Use Device named above. | |
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| **PATIENT - (print name) SIGNATURE DATE** | | | | |
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| **LEGALLY AUTHORIZED REPRESENTATIVE OF SIGNATURE DATE** | | | | |
| **PATIENT AND RELATIONSHIP TO PATIENT** | | | | |
| **(print name and relationship)** | | | | |
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| **PATIENT'S TREATING PHYSICIAN (print name) SIGNATURE DATE** | | | | |
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