**Consent Form Module: Humanitarian Use Device (HUD)**

**If the IRB agrees that this HUD is for treatment use, this module can be inserted into or appended to the patient’s clinical consent.**

**If the HUD is part of a research study, the INTRODUCTION section of this module can be inserted into the clinical research informed consent template.**

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

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**INTRODUCTION**

A humanitarian use device (HUD) is defined by the Federal Food, Drug and Cosmetic Act as a device intended to help patients in the treatment and diagnosis of diseases or conditions that affect or are seen in fewer than 8,000 people in the United States per year.

The use of this HUD (name of the HUD) has been approved by the federal Food and Drug Administration for the treatment of (patient’s condition) but its effectiveness has not been scientifically shown.

You are being asked to give your consent for use of an HUD by your physician because you have (condition) and you have not improved with available treatments. Your participation is voluntary. The (device/product) use will be under the direction of (investigator) in the department of (Department). Other physicians and professional staff persons may assist (him/her) in the use of this (device/product).

# PURPOSE

This is not a research study.

Description of the purpose, use and indications for the device

# PROCEDURES

Description of the procedures involved in the use of the device

# RISKS AND DISCOMFORTS

Summary of risks, potential adverse events.

# RISKS TO PREGNANT WOMEN

Describe risks, precautions.

# BENEFITS

Indicate the potential benefit(s) to using the HUD

# FINANCIAL RISKS

You or your insurance carrier will be responsible for the cost of hospitalization and all procedures, including use of the HUD. Insurance companies may or may not pay for this device because it is not approved. The rest of the medical care that you will receive is considered standard of care for your situation and thus would be recommended regardless of your decision to participate. You may contact (investigator)at (phone #)if you have any questions.

# ALTERNATIVE PROCEDURES

List alternative treatments available for the condition.

# PARTICIPATION

Your participation is entirely voluntary. If you decide to not have the (name of the HUD) your decision will have no effect on the quality of current or future medical care you receive. If any important new information is found that may affect your desire to participate in the (treatment with the HUD),you will be told about it right away. You can then decide if you want to participate.

# COMPENSATION FOR INJURIES

If you are injured as result of the use of this HUD, you or your insurance company will be billed for the costs of treatment. Froedtert Hospital and the Medical College of Wisconsin will not pay for the cost of medical treatment. This does not prevent you from attempting to recover these costs through the legal process.

# FURTHER INFORMATION

If you have further questions, call (investigator) at (phone #).

# CONFIDENTIALITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) protects your health information. Your protected health information (PHI) includes information that specifically identifies you, your relatives, household members or employers, such as names, addresses, dates, social security numbers, or account numbers.

Medical Records that identify you will be kept confidential as required by law. Federal Privacy regulations provide safeguards for privacy, security, and authorized access to your health information. As part of this HUD (investigator) may report the following protected health information (list all PHI to be reported) concerning the use and results of the HUD to (name of device sponsor) for a period of (indicate number of years).

Your authorized health information, examples of which are noted above, may be accessed and/or copied by other reviewers for the purpose of quality assurance. These reviewers may include third party payers, (name of device sponsor), representatives of the Food and Drug Administration (FDA), the Office for Human Research Protections in the U.S. Department of Health and Human Services, the Medical College of Wisconsin Human Research Review Committee, Froedtert Hospital and its Institutional Review Board or those required by law. (Investigator) and his (medical/surgical) team agree to protect your health information be using and disclosing it only as permitted in the consent and as directed by State and Federal law.

The persons or organizations that receive your disclosed authorized health information may re-disclose this information and will not be covered by the HIPAA regulations.

**To voluntarily participate in the use of this HUD, I must confirm the following and sign below:**

Include appropriate bullet points

**Signatures:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Subject's Name** *please print* | **Subject's Signature** | **Date** |
|  |  |  |
| **Name of Legally Authorized Representative** (if applicable**)**  *please print* | **Signature of Legally Authorized Representative** | **Date** |
|  |  |  |
| **\* Name of person discussing/ obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | **Date** |

*\* A member of the study team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent.*

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|  |  |  |
| **Name of Principal Investigator** *please print* | **Signature of Principal Investigator** | **Date** |