*This template is for use of Humanitarian Use Devices (HUD).*

*Additional modules for special cases can be found on the IRB website.   
These modules can be inserted into the appropriate project-specific text boxes.*

**Instructions**

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 and any additional applicable sections of this module can be inserted into the clinical research informed consent template or this document may be used as a separate form.

**< Medical College of Wisconsin // Children’s Wisconsin >**

**INTRODUCTION TO THE INFORMED CONSENT**

<Humanitarian Use Device Title>

<Treating Physician>

<Department>

<Telephone Number>

<<Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226>>

//

<<Children’s Wisconsin

8915 W Connell Ct

Milwaukee WI 53226>>

Insert the following language if this HUD will be used for a minor.

**Subject**: This form tells you why this Humanitarian Use Device (HUD) is being proposed, what will happen if you agree, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this project or not. If you are under the age of 18, your parent or guardian needs to give their permission for use of this device.

**Parent/Guardian**: A Humanitarian Use Device (HUD) is being proposed to help treat your child. This form tells you why this HUD is being proposed, what will happen if the HUD is used, and possible risks and benefits to your child. If there is anything you do not understand, please ask questions. Then you can decide if you want your child to undergo treatment using this HUD. The word “you” in this form refers to your child.

CONSENT TO PARTICIPATE

**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 (HUD doctor) in the department of (Department). Other physicians and professional staff persons may assist them in the use of this (device/product).

# PURPOSE

This is not a research project.

Description of the purpose, use and indications for the device

# B1. PROCEDURES

Description of the procedures involved in the use of the device

# RISKS AND DISCOMFORTS

In this section, list the physical risks in language that is understandable to the patient. The explanation of risks should be reasonable and should not minimize reported adverse effects.

Risks should be divided into categories of: (i) very likely, (ii) less likely, but serious. Provide the likelihood of the risk as a percentage or absolute numbers (x out of xx people) whenever possible. State whether side effects are temporary or permanent.

Summary of risks, potential adverse events.

# RISKS TO PREGNANT WOMEN

If this consent is being used for minors, risks related to pregnancy should be addressed as it would be in a clinical setting.

In this section, list the physical risks in language that is understandable to the patient. The explanation of risks should be reasonable and should not minimize reported adverse effects.

Risks should be divided into categories of: (i) very likely, (ii) less likely, but serious. Provide the likelihood of the risk as a percentage or absolute numbers (x out of xx people) whenever possible. State whether side effects are temporary or permanent.

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. It is recommended that you contact your insurance company to see what they will and will not pay for. Your doctor can provide you with information about how to do this. You may contact (HUD Doctor)at (phone #)if you have any questions.

# ALTERNATIVE PROCEDURES

**In this section briefly explain any pertinent alternatives to the HUD. While this should be more than just a list of alternatives, a full risk/benefit explanation of alternatives may not be appropriate to include in the written document. The person(s) obtaining the patient's consent, however, must be able to discuss available alternatives and answer questions that the patient may raise about them.**

List alternative treatments available for the condition.

# YOUR CHOICE TO USE THIS HUD

Your agreement to use (name of the HUD) is entirely voluntary. If you decide to not have the HUD used, your decision will have no effect on the quality of current or future medical care you receive.

# FURTHER INFORMATION

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

# CONFIDENTIALITY AND PRIVACY

**This section should be included if this HUD is used as part of a research project and this form is being used separately from the clinical research consent form.**

The following language should be inserted if applicable and if use of this HUD is occurring at MCW, Froedtert, or Versiti by MCW, Froedtert or Versiti Faculty and Staff.

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, (Doctor) 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.

The following language should be inserted if applicable and if use of this HUD is occurring at Children’s Wisconsin by Children’s Wisconsin Faculty and Staff.

Your record of this procedure will be kept private, or will be disclosed only with your permission unless required by law. The use of the (name of the HUD) in your treatment is not connected to any research study to determine the safety and effectiveness of the HUD. No individually identifiable information will be released to the manufacturer of the device or to the Food and Drug Administration.

Information about receiving the (name of the HUD) may be reviewed by a Children’s Wisconsin billing representative as part of normal hospital operations.

The FDA requires that a yearly report about the use of the HUD be submitted to the Institutional Review Board (IRB), the human subject protection committees that oversee research done at CW. Any reports of problems associated with the use of this HUD will also be reported to the IRB, and this report could identify you.

Any information related to receiving the HUD will be treated confidentially to the extent required by the applicable laws and regulations. Unfortunately, we cannot promise complete confidentiality.

**CONSENT TO USE OF HUD**

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

* I have read this form and the HUD has been explained to me.
* I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
* I agree to the use of the HUD described above.

**IMPORTANT:** You will receive a signed and dated copy of this consent form and a copy will be placed in your medical record. Please keep it where you can find it easily. It will help you remember what we discussed today.

***Signature line instructions:***

*Generally, the patient or parent’s signature is sufficient. If the patient is a minor delete the signature lines for adult patient.*

*Legally Authorized representative should be used if an adult subject has decreased decisional ability.*

***Date or Date & Time: Time is optional to include; if included, must be completed by each signer.***

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| --- | --- | --- |
|  |  |  |
| **Adult Patient's Name** *please print* | **Adult Patient's Signature** | **Date**/**Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of <Parent/Guardian> // <Legally Authorized Representative>>, if applicable**  *please print* | **Signature of <Parent/Guardian> // <Legally Authorized Representative>** | **Date/Time** |
|  |  | |
| ***Name of Patient*** *please print* | ***Relationship to Patient*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)* | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\* Name of physician discussing/ obtaining consent** *please print* | **Signature of physician discussing/obtaining consent** | **Date** |

***Attachment 1 is optional. Delete if not needed***

Attachment 1 – Details of project schedule and procedures