Please check one of the following:

\_\_\_\_\_ You are an adult patient providing consent for Humanitarian Use Device (HUD) treatment

\_\_\_\_\_ You are the parent or guardian granting permission for HUD treatment of a child.

If the participant is a child the use of "you" refers to "your child"

**What you should know about this Humanitarian Use Device (HUD):**

We have determined that you have ***[NAME OF CONDITION],*** which is a rare condition. We believe that ***[SPECIFY DEVICE]*** may help you. There is currently no other treatment that we believe would be as helpful.

[SPECIFY DEVICE] is a Humanitarian Use Device (HUD). A HUD is a device that researchers can’t test in studies, because fewer than 8,000 people have the condition it’s used to treat. The U.S. Food and Drug Administration (FDA) has approved the use of HUDs for the clinical treatment of patients, even though HUDs don’t go through the same amount of testing that other products do. The FDA believes that HUDs are likely to be safe and will probably benefit patient,

This device has been approved for ( insert use). We are proposing to use the device for a purpose that it was not approved for because we feel it may also be useful for your condition

The purpose of this form is to help you understand how [*SPECIFY DEVICE*] works and to give you an opportunity to decide whether you want us to use it to treat you.

Before you sign this form, be sure you understand how (*SPECIFY DEVICE*]*)* relates to your condition, as well as the risks and possible benefits

Name and nature of the device:

Why is this device is being recommended?

[*SPECIFY DEVICE*] is used to treat [*NAME OF CONDITION*] by [*DESCRIBE WHAT THE DEVICE DOES—e.g., “connecting the two chambers of the heart for better blood flow*”].

What are the procedures involved with receiving this device?

What is usually done for patients who have this type of disease or condition?

Standard treatments for [*NAME OF CONDITION*] include [*LIST STANDARD TREATMENTS*]. We will be glad to talk to you about your other treatment options.

 What are the risks of being treated with this device?

What are the possible benefits of being treated with this device?

Will receiving [*SPECIFY DEVICE*] cost you any money?

The [*SPECIFY DEVICE*] will be provided free of charge to you.

 or

Your insurance plan may or may not pay for treatment with this [name of the device]. If your insurance plan does not pay for this treatment, you will be billed for the cost of the [name of the device] and all related doctor and hospital costs, including any treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

How will your personal information be shared?

Your doctor is asking for your permission to gather, use and share information about you while you are receiving the [*SPECIFY DEVICE*]. If you decide not to give your permission, you cannot receive the [*SPECIFY DEVICE*] but you can continue to receive regular medical care at Boston Children’s Hospital

If you sign this form, we may collect any or, all of the following information about you:

•Personal information such as name, address and date of birth

•Your health information if required for the receiving [*SPECIFY DEVICE*] This may include a review of your medical records and test results from before, during and after you receive the [*SPECIFY DEVICE*].

**Who will see your Information?**

Your participation in this research study may be noted in your electronic medical record. If you do not have an existing medical record, one may be created. Information placed in your medical record may include the informed consent or the results of tests or assessments we collect during the research. This could be viewed by staff from Boston Children’s Hospital, study monitors and others who provide oversight of the study. Everyone who sees this information is required to keep it confidential in accordance with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.

Your health information is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA). In general, anyone who is involved in this HUD treatment may see health information about you. For example, the following people might see information about you:

* Medical staff at Boston Children’s Hospital involved in your HUD treatment
* Other people at Boston Children’s Hospital involved in the oversight of HUD treatment such as the Institutional Review Board (IRB).
* Government agencies (such as the Food and Drug Administration), safety monitors, or the company that manufactures the HUD.
* Your health insurer, for portions of the research and related care that are considered billable.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children’s Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children’s Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

**Your privacy rights:**

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the treating physician. The physician’s name and contact information may be found in this consent form.

If you do cancel your authorization to use and disclose your information, no further information about your use of the HUD will be collected. Your revocation (cancellation) would not affect information already collected, or any information we disclosed before you wrote to the treating physician to cancel your authorization.

***INSTRUCTIONS:*** *Please edit the Contact Information table and signature sections as pertinent to the study.*

**Contact Information**

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this HUD treatment. I know:

|  |  |  |
| --- | --- | --- |
| 🚹 I can call… | **🕾** At | **❓** If I have questions or concerns about |
| Treating Physician | Phone: | **[Insert Contact #]** | ▪ General questions about the HUD ▪ HUD related injuries or emergencies▪ Any HUD- related concerns or complaints |
| **[Insert Physician Name]** | Pager: | 617-355-7243 **[Pager #]** |
|  |  |
| BCH Institutional Review Board  | Phone: | **617-355-7052** | Rights of a participant Use of protected health information.Any concerns or complaints.If treating physician contact cannot be reached.If I want to speak with someone other than treating physician  |
|  |  |  |

**Documentation of Informed Consent and Authorization**

**Parent/Legal Guardian Permission (if applicable)**

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

**Adult Participant (if applicable)**

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Adult Participant (***18+ years)*

**Adult Participant: If decisionally impaired (if applicable)**

**Legal Authorized Representative/Guardian**

I give permission for the person I am authorized to represent to participate in this treatment and for the use of associated protected health information as described above (HIPAA).

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Legal Guardian** Print Name

◼ Relationship to Participant \* *(This order must be followed. If there is a court appointed guardian, this is who needs to provide consent. If not, a health care proxy, followed by durable power of attorney and lastly, family members)*

 [ ]  Court-Appointed Guardian

[ ]  Health Care Proxy (Attach Proxy and ensure there is express authority to make health care decisions inclusive of research.)

[ ]  Durable Power of Attorney (POA) (Durable POA may be limited to specific areas. Attach Durable POA and ensure that it covers research.)

 [ ]  Family Member/Next of Kin, (in order of preference: spouses, parents, and adult children)

 Specify relationship\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Adult Assent** (if applicable)

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date (MM/DD/YEAR) Signature of **Adult Participant**

[ ]  CHECK if Adult Participant’s assent **not** obtained above, and specify reason below:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Treating Physician /or Associate’s Signature**

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**