If you are using Epic, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

# **HUMANITARIAN USE DEVICE INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM**

**Protocol Title**:

Application No.:

**Treating Physician**:

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

* You are being asked to allow the use of a HUD called \_\_\_\_\_\_\_\_\_\_\_\_\_.This consent form explains the risks and benefits of the treatment. Please read it carefully and take as much time as you need.
* Ask your treating physician to explain any words or information in this informed consent that you do not understand.
* During treatment, we will tell you if we learn any new information that may cause you to change your mind about receiving treatment with this HUD.
* When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children’s Hospital.

1. **Why will the HUD be used?**
2. **What will happen if you agree to the use of the HUD for your treatment?**
3. **What are the risks or discomforts of using the HUD?**
4. **Are there risks related to pregnancy?**
5. **What are the potential benefits from the use of the HUD?**
6. **What are your options if you do not want to be treated with this HUD?**
7. **Will it cost you anything to be treated with the HUD?**

If your insurance company will not pay for the procedure or the device, you will be responsible for these costs. If your insurance company will pay for only a portion of the procedure or the device, you will be responsible for the costs that insurance does not cover. Your treating physician or the medical team will contact your insurance company to see if they will pay for the device and any associated procedural costs.

1. **Can you or your treating physician decide not to allow the use of the HUD for your treatment?**

You can always change your mind at any time. If you wish to stop, please tell us right away. Stopping this treatment will not prevent you from getting other medical care*.* If your treatment with the HUD needs to be stopped for reasons related to your safety or other medical necessity, your treating physician will discuss with you the reason for stopping treatment and your options for continued care.

1. **How will your privacy be protected?**

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

Clinicians assisting in your treatment with the HUD will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Clinicians assisting in your treatment and other people at Johns Hopkins will know your identity and may share your information with people outside of Johns Hopkins when required. Some examples are government agencies (such as the Food and Drug Administration), safety monitors, or the company that manufactures the HUD.

We cannot do this procedure without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not receive the HUD.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

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 by phone or in writing. If you contact by phone, you must follow-up with a written request that includes your contact information. The physician’s name, address, phone and fax information are on page one of 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.

1. **Who will pay for treatment if you are injured as a result of the use of the HUD?**

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from the use of the HUD. However, other medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a HUD-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

1. **What other things should you know?**
   * + 1. **What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

* Doctors
* Nurses
* Ethicists
* Non-scientists
* People from the local community.

HUDs may only be used if approved for use by the IRB.

When the Johns Hopkins Medicine IRB reviews the use of a HUD at another site, that site (institution) is solely responsible for the safe conduct of the treatment and for following the protocol approved by the Johns Hopkins Medicine IRB.

* + - 1. **What do you do if you have questions or concerns about the HUD?**

Call your treating physician, Dr. \_\_\_\_\_\_ at \_\_\_\_\_\_. If you cannot reach the treating physician or wish to talk to someone else, you can call the IRB office at 410-955-3008.

* + - 1. **What should you do if you have a HUD-related problem or injury?**

If you have a HUD-related problem or injury, call *designated physician* at *insert telephone number* during regular office hours and at *insert phone or pager number available 24 hours* after hours and on weekends.

*If you insert a pager number, include the following instructions:* **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

* + - 1. **What happens to Data and Biospecimens collected as a result of the use of the HUD?**

If you receive the HUD, you should understand that you will not own any biospecimens or data we collect in relationship to the use of the HUD, and should clinicians use them to create a new product or idea, you will not benefit financially.

1. **What does your signature on this consent form mean?**

By signing this consent form you are not giving up any legal rights. Your signature means that you understand the information given to you about the HUD in this form, you accept the provisions in this form, and you agree to receive the HUD.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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

Signature of Patient (Print Name) Date/Time

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

Signature of Person Obtaining Consent (Print Name) Date/Time

**NOTE**: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE TREATING PHYSICIAN; A COPY MUST BE GIVEN TO THE PATIENT; IF YOU ARE USING EPIC FOR THIS HUD A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PATIENT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF PATIENTS.**