University of Michigan

Consent for Use of an FDA Designated

Humanitarian Use Device (HUD)

### Information About tHIS DOCUMENT

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 no more 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 patients.

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.

Insert the following if applicable:

To make sure you have enough information to decide, we are also giving you information from the company that supplies [SPECIFY DEVICE].

Insert conflict of interest information here if applicable (e.g., “The University of Michigan owns shares in the company that makes [SPECIFY DEVICE] and may profit from its use”).

Before you sign this form, be sure you understand how [SPECIFY DEVICE] relates to your condition, as well as the risks and possible benefits of using it.

### General Information About The TREATMENT

## Name and nature of the device:

If the project is sponsored with outside funding, change the header below to

**2. Title, eResearch number, and sponsor of the HUD project:**

## Title and eResearch number of the HUD project:

HUM#

## 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 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.

### HOW information about you will be shared

## If you give us permission to use [SPECIFY DEVICE], we will give the following information about you to [COMPANY NAME], which is the manufacturer or supplier of the device:

Describe or list information.

## [COMPANY NAME] may be required to provide the following information to FDA:

Describe or list information.

## We may provide the Institutional Review Board of the University of Michigan Medical School (IRBMED) with the following kind(s) of information:

* Any problems that occur when you are treated with this device.
* [ANY OTHER INFORMATION THAT APPLIES]

We can usually provide this kind of information using codes, so that IRBMED doesn’t find out your name. However, IRBMED can review your medical record if they need to.

For more information about our use and disclosure of protected health information, please refer to our Notice of Privacy Practices. You should already have received a copy. You may also find this notice online, at http://www.med.umich.edu/hipaa/npp.htm.

### RISKS AND BENEFITS

## What are the risks of being treated with this device?

Describe or list risks. If appropriate, include measure to monitor risk.

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

Describe the anticipated benefit to the patient.

### record of Information provided

1. **What documents will I receive?**

Your signature in the next section means that you have received copies of all of the following documents:

This consent form (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential file and may be entered into your regular University of Michigan medical record.)*

Company information about the device, if available.

If you provide the subject with other information, such as a Notice of Privacy Practices or information about advance directives, list the documents on the line below. Otherwise, you may delete the bullet.

Other (specify):

### SIGNATURE

Name of Patient:

Signature Patient:

Patient ID: Date of Birth:

*If patient is not able to give consent for use of this device, use the section below:*

**Legal representative or guardian**:

I have reviewed the information printed on this form and in the attached materials. I have been given copies of all of these. I have discussed this device, its risks and potential benefits, and alternatives with [NAME OF PERSON RESPONSIBLE FOR CONSENTING PATIENT]. My questions so far have been answered. I also understand that I will receive a copy of this document at the time I sign it.

Signature of Person Legally

Authorized to Give Consent: Date:

Name (Print legal name):

Address and Phone:

Relationship to Patient:

Parent  Legal Guardian

Other:

**Principal Investigator or Designee –** The following signature block is to ensure that the patient was given sufficient information to be able to freely consent. This signature is optional, unless required by the sponsor. This signature should be from the person who actually conducted the informed consent and is familiar with the device, such as the physician or other qualified member of their team.

**Physician or Designee**

I have provided this patient and/or his/her legally authorized representative(s) with information about this device that I believe to be accurate and complete. The patient and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the device, including risks and benefits of its use.

Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_