Consent for Use of a FDA Designated

 Humanitarian Use Device (HUD)

**Adult to Receive [Name of HUD]**

**or**

**Parents’ or Guardians’ Permission for Your Child to Receive [Name of HUD]**

(for parent/Legal guardian to sign on behalf of Minor less than 7 years of age)

or

**Agreement of a Child to Receive [Name of HUD]**

(for use of Minor 15-17 years of age)

###### Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Medical Record #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- |
| Name, address, telephone # of UVA Investigator |  |

## What is the purpose of this form?

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 4,000 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.

**If applicable,** [We are also giving you information from the company that supplies (specify device).]

**If applicable,** insert conflict of interest information here; otherwise delete.

Before you sign this form, be sure you understand how [SPECIFY DEVICE] relates to your condition, as well as the risks and possible benefits. If you want to receive the device, you will need to sign this form. You will be given a copy of this form.

## 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”].

1. 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.

1. **What are your responsibilities if you receive this device?**

 You and have certain responsibilities to help ensure your safety. These responsibilities are listed below:

* You must be completely truthful about your health history.
* Follow all instructions given.
* You or should tell the doctor about any changes in your health or the way you feel.

During the time you are receiving [SPECIFY DEVICE], Dr. [Name of UVA PI] will let you know of any test results that may be important to your health.  In addition, [Name of UVA PI] will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue receiving the device.

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

1. **What are the possible benefits of being treated with this device?**
2. Will you be paid for receiving the device?

You will not get any money for taking part in this expanded access program.

1. **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.

**[If applicable]** You will be responsible for the cost of travel to come to the clinic at UVA and for any parking costs.

1. **What if you are hurt?**

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of receiving this device, you may contact the Doctor providing you with the treatment or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of participating in treatment, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

1. **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 UVA.

**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]. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

**Who will see your private information?**

Some of your information, such as side effects from the [SPECIFY DEVICE] will be shared with [list manufacturer] and the Food and Drug Administration (FDA). You will not be personally identified in any correspondence. We may also provide information to the UVA Institutional Review Board (IRB) if you experience any serious health related problems that occur when you are receiving the treatment.

**What if you sign the form but then decide you don't want your private information shared?**

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the UVA PI listed on this form. Your doctor will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. This means that everyone who is allowed to see your medical records will be able to find out that you received this [SPECIFY DEVICE]and is done so your regular doctors will know what you receive as part of your clinical care. If you have other health problems after you receive [SPECIFY DEVICE], they will be able to treat you properly.

**Please contact your treating physician listed below to:**

* Obtain more information about the [SPECIFY DEVICE]
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Stop any procedures related to receiving the [SPECIFY DEVICE]
* Express a concern about the [SPECIFY DEVICE]

**Principal Investigator:**

**[Name, address, phone #]**

**What if you have a concern about this process?**

You may also report a concern about this process or ask questions about your rights by contacting the Institutional Review Board listed below.

 University of Virginia Institutional Review Board for Health Sciences Research

PO Box 800483 Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of your doctor, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials review your concern. When reporting a concern, you do not have to give your name.

1. **SIGNATURES**

*Note: Contact the IRB if you have questions about which signature sections are relevant for your treatment.*

**What does your signature mean?**

Before you sign this form, please ask questions about any part of the [SPECIFY DEVICE] that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to receive the [SPECIFY DEVICE]. You will receive a copy of this signed document.

**Consent from Adult**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(PRINT) |  | \_\_\_\_\_\_\_DATE |  |  |

**To be completed by participant if 18 years of age or older.**

If an interpreter is involved in the consent process because the potential patient does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

**Person Obtaining Consent**

By signing below, you confirm that you have fully explained this treatment to the potential patient, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

**Assent from Child**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(PRINT) |  | \_\_\_\_\_\_\_DATE |  |  |
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**Person Obtaining Assent of the Child (less than 18 years of age)**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

By signing below, you confirm that the treatment has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING ASSENT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING ASSENT(PRINT) |  | \_\_\_\_\_\_\_DATE |

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**If an interpreter was used to explain this treatment to a potential patient who is a child, the interpreter must sign and date the line above**

**Parental/ Guardian Permission**

By signing below, you confirm you have the legal authority to sign for this child.

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| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARENT/GUARDIAN(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARENT/GUARDIAN(PRINT NAME) |  | \_\_\_\_\_\_DATE |  |  |

**If an interpreter is involved in the consent process because the parent/guardian does not speak English well or at all, the parent/guardian should NOT sign on the line(s) above – leave the line(s) above blank. Instead, the parent/guardian should sign the IRB approved Short Form written in the language they can understand.**

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

**Person Obtaining Parental/Guardian Permission**

By signing below, you confirm that you have fully explained this treatment to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME) |  | \_\_\_\_\_\_\_\_DATE |

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**Surrogate Consent**

In the event the adult participant is unable to give informed consent for participation in this treatment:

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PERSON GIVING CONSENT FOR PARTICIPANT DATE

(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If an interpreter is involved in the consent process because the surrogate does not speak English well or at all, the surrogate should NOT sign on the line above – leave this line blank. Instead, the surrogate should sign the Short Form written in the language they can understand.**

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**Person Obtaining Consent of the Surrogate**

By signing below, you confirm that you have fully explained this treatment to the potential patient’s surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

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**Attending Physician Approval**

I am the doctor that provides medical care for this patient. I believe that his/her health might be helped by receiving this treatment. I approve his/her participation in receiving this treatment.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ATTENDING PHYSICIAN(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ATTENDING PHYSICIAN(PRINT NAME) |  | \_\_\_\_\_\_\_\_DATE |

**Note: If the UVA investigator is also the attending physician for the patient, they may also sign here as the attending physician.**

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**Person Obtaining Assent of the Adult Patient**

The patient is unable to give assent due to the following reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR**

By signing below, you confirm that the treatment has been explained to the adult patient, all questions have been answered and the adult patient has not demonstrated resistance or dissent by word or gesture to continue receiving treatment. You also confirm that if the patient demonstrates resistance or dissent at any point while receiving treatment that they will not be subject to any additional interventions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING ASSENT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING ASSENT(PRINT) |  | \_\_\_\_\_\_\_DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient’s surrogate in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**If an interpreter was used to explain this treatment the interpreter must sign and date the line above.**

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**Consent of the Patient to Continue to receive treatment**

Your legal representative gave his/her permission for you to receive emergency treatment. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this treatment. The decision is up to you. Before you sign this form, please ask questions about any part of this treatment that is not clear to you. When you sign below, you are saying you understand the information we gave you about the treatment and in this form.

**If you sign this form it means that you agree to continue being in the treatment.**

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

PARTICIPANT PARTICIPANT DATE

(SIGNATURE) (PRINT)

**If an interpreter is involved in the consent process because the patient does not speak English well or at all, the patient should NOT sign on the line above – leave this line blank. Instead, the patient should sign the Short Form written in the language they can understand.**

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**Person Obtaining Consent of the Patient**

By signing below, you confirm that you have fully explained this treatment to the patient, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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

PERSON OBTAINING PERSON OBTAINING DATE

CONSENT CONSENT (PRINT)

(SIGNATURE)

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**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INTERPRETER(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

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**Signature of Impartial Witness**

**If this consent form is read to the patient because the patient is blind or illiterate, an impartial witness not affiliated with the treatment doctor must be present for the consenting process and sign the following statement. The patient may place an X on the Participant Signature line above.**

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the treatment.   I also agree that the **identified individual(s)** freely gave their informed consent to participate in this treatment.

**Please indicate with check box the identified individual(s):**

[ ]  Patient [ ]  Parent(s)/Guardian of the patient [ ]  Patient’s surrogate

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_IMPARTIAL WITNESS(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_IMPARTIAL WITNESS(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**Notification of My Health Care Provider**

Your health care provider will be notified of your participation in this treatment.