Louisiana State University Health Sciences Center in New Orleans

Consent to Undergo Treatment with a Humanitarian Use Device

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| **INSTRUCTIONS:**   * Use this consent template only when treating a patient with a Humanitarian Use Device (HUD). * Update the version date in the header each time you make a change. * Placeholders and instructions are written in **blue text**. * **Text in black** is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across consent forms. This text is optimized for readability and grade-level comprehension. * As much as possible, write in common, everyday language that can be understood by a participant with an 8th to 10th grade education, similar to the style used in popular news magazines and newspapers. Check the readability level of the document or a subset of the document in [Word](https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#__toc342546555) or [StoryToolz](https://storytoolz.com/readability). * Delete all **blue text** and this **table** before finalizing the consent document. |

**TITLE:**       [Application title, name of device, or title on HDE]

**TREATING PHYSICIAN:**       [Name and credentials]

**DAYTIME PHONE #:**

**24-HOUR PHONE #:**

**HUD MANUFACTURER:**

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 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 patients.

The purpose of this form is to help you understand how [specify device] works and to give you an opportunity to decide whether or not you want us to use it for your treatment.

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 your condition and the treatment

[Provide a brief description of the patient’s disease or condition including the standard treatment(s), if any, for the condition;

Provide a concise description of the device including the specific indication(s) for its use and why it is being recommended for this patient.]

What will happen if I agree to this HUD treatment?

If you agree to this treatment, the following procedures will be performed on you:

[Provide a concise description of all procedures, including placement of the device, in chronological order and in enough detail to give a clear picture of what the patient will experience during the treatment.]

Are there potential risks associated with this HUD treatment?

The possible risks and/or discomforts associated with the procedures described above and the use of the device include:

[Using simple, short sentence, describe the risks involved with the placement and use of the device in language that is understandable to a lay person. 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.]

What are the possible benefits of this HUD treatment?

[Describe any anticipated benefits of use of this device, with particular reference to the patient’s disease or condition.]

What other choices do I have if I do not agree to this treatment?

If you do not agree to this treatment or if the treatment is stopped early, the following options are available to you:

[Describe the therapeutic alternatives available to the patient. Consent documents should 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].

Will information about my treatment be shared with anyone?

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 the information to be provided to the manufacturer.]

[Company name] may be required to provide the following information to FDA:

[Describe the information to be provided to the manufacturer.]

The FDA requires that a yearly report about the use of the HUD be submitted to the LSUHSC-NO Institutional Review Board (IRBs), the committee that is responsible for the protection of individuals participating in human research at LSUHSC and affiliated institutions. 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 your receiving the HUD will be treated confidentially to the extent required by applicable laws and regulations. Unfortunately, we cannot promise complete confidentiality.

Who is responsible for the cost of this HUD treatment?

You or your insurance provider will be responsible for all cost associated with the procedures and use of the [device name].You will also be responsible for all costs related to the treatment of your [name of disease or condition]. Your physician will discuss the costs of this procedure with you.

Who can I talk to?

If you have questions, suggestions, or concerns regarding you treatment with the HUD; or think the treatment has hurt you; or you want to stop the treatment: please talk to the treating physician whose contact information is provided at the top of this document.

If you have questions about your rights; or want to discuss problems, concerns or questions; or obtain information or offer input: you can contact the Chancellor of the LSU Health Sciences Center of New Orleans at (504) 568-4801.

Your consent

The placement and procedures involved in the use of the Humanitarian Device have been fully explained to me. I have had a chance to ask any questions I have about the device and procedures and I have been told that any additional questions I may have will be answered at any time by my physician. I also have been informed that this device has been approved for clinical treatment by the FDA and I am not a subject in a research study.

By signing this document, I acknowledge or am aware that:

* I do not waive any of my legal rights by signing this consent document.
* I will receive a copy of the signed consent form and a copy will be placed in my medical records.
* I will receive [list any other documents that will be given to the patient such as the Patient Information Brochure from the device manufacturer; otherwise delete this bullet].

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| **Signature of Patient:**  *I agree to receive the Humanitarian Use Device named above.* | | |
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| Name of Patient |  |  |
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| Patient Signature |  | Date of Signature |
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| **Signature of Legally Authorized Representative (LAR):**  *I am a legally authorized representative of the patient named below. I agree for the patient to receive the Humanitarian Use Device.* | | |
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| Name of Patient |  |
|  |  |
| Name of LAR |  |  |
|  |  |  |
| Signature of LAR |  | Date of Signature |
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| **Signature of Treating 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.* | | |
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| Name of Treating Physician or Designee |  |  |
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| Signature of Physician or Designee |  | Date of Signature |
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