Central Michigan University

Children’s Hospital of Michigan

Consent for Expanded Access Use of an FDA Investigational Agent

### Information About Expanded access treatments and tHIS DOCUMENT

We have determined that you have [NAME OF CONDITION] [EMERGENCY USE ONLY: which is a life-threatening disease]. We believe that [SPECIFY NAME OF DRUG/DEVICE] may help you. There is currently no other approved and common treatment that we believe would be as helpful. The approved and commonly used treatments are unlikely to prolong your life.

[SPECIFY DEVICE] is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it’s safe and effective. Because this device is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use.

The purpose of this form is to help you understand how [SPECIFY NAME OF DEVICE] works and to give you an opportunity to decide whether you want us to use it to treat you. We may also give you information from the company that supplies the device.

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

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

### Specific Information About The TREATMENT

## Name of Doctor Providing Treatment with the [DRUG/DEVICE]:

## Name of the [DEVICE]:

[THE DEVICE MUST BE CLEARLY IDENTIFIED SO THAT IT CAN’T BE CONFUSED WITH ANOTHER DEVICE, EITHER FDA-APPROVED OR STILL UNDER INVESTIGATION.]

## Title of the Expanded Access project:

**2.4 Project Number:**

## 2.5 Why is this [DEVICE] being recommended?

[SPECIFY NAME OF 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”].

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

Currently approved products and treatments for [NAME OF CONDITION] include [LIST AND DESCRIBE APPROVED PRODUCTS AND TREATMENTS]. We will be glad to talk to you about your other treatment options.

### Costs associated with this treatment

*Select one of the following for 3.1 and delete the other options, as well as all bracketed instructions.*

*After making the appropriate selection, delete this text box.*

**3.1 [*For investigational drug or device if patient will be responsible for ALL costs:***

**(charging the patient requires prior FDA approval):]**

You or your insurance will be responsible for the cost of all care associated with the procedure[*s*] and the [DRUG/DEVICE] itself. This includes the cost of treatment if the [DRUG/DEVICE] makes you sick or causes you injury. It is possible that your insurance will not pay for the cost of the [*include as applicable:  drug, device, procedure to implant the device*] because the [DRUG/DEVICE] is considered investigational.  If that occurs, you will be responsible for all costs, and these costs may be substantial.

**3.1 [*For investigational drug or device if sponsor is providing free drug/device:*]**

The [DRUG/DEVICE] will be provided to you at no cost.  You or your insurance company will be responsible for the remaining costs related to this treatment, including the cost of treatment if the [DRUG/DEVICE] makes you sick or causes you injury.  You will be responsible for any costs your insurance does not cover.  Please note that your insurance is not obligated to pay for any care or treatments consequent to the use of [DRUG/DEVICE], unless it is specifically required to do so by law or contract. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

*Note: The following option will apply only in rare cases:*

**3.1 *[For investigational drug or device if sponsor will cover costs both of the drug/device and of treatment for drug/device-related injury or illness; such instances are uncommon and involve additional agreements between the sponsor and the Office of Research and Sponsored Projects (ORSP):]***

The [DRUG/DEVICE] will be provided to you at no cost.  The sponsor of the study will also reimburse or otherwise pay for the treatment of any side effect, adverse reaction, illness, or injury to you resulting from the administration of study [DRUG/DEVICE] or procedure and/or assessment performed in accordance with the [DRUG/DEVICE] protocol.

**3.2** By signing this form, you do not give up your right to seek payment if you are harmed as a result of receiving this treatment.

### HOW information about you will be shared

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

## 4.2 We may provide the Institutional Review Board of Central Michigan University (CMU) with the following kind(s) of information:

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

We usually provide this information to CMU with a code instead of using your name. In some instances, however, CMU may need to review your medical records and may request your name from your doctor to access your records.

**4.3** University, Food and Drug Administration (FDA), and/or other government officials may also need the information to make sure that the device is used in a safe and proper manner.

For more information about our use and disclosure of protected health information, please refer to the Central Michigan University’s Notice of Privacy Practices. This notice should already have been made available to you and you may also find this notice online, at \_\_\_\_

RISKS AND BENEFITS

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

[THIS SECTION MUST SPECIFICALLY INCLUDE THE POTENTIALLY WORST OUTCOME OF THE TREATMENT]

It is possible that new, unanticipated, different, or worse symptoms will result from using this device. This device can also hasten death.

**Additional language for COVID-19 projects or projects with COVID-19-related components**

On March 10, 2020, the Secretary of Health and Human Services (“HHS”) published the Notice of Declaration Under the Federal Government’s 2005 Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures against COVID-19. The PREP Act covers studies with any products that are approved, cleared, or licensed by FDA; authorized for investigational use under IND or IDE; or used for emergency use.

If your project involves any COVID-19-related procedures and fall under above categories, insert the following:

Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study.

If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to <https://www.hrsa.gov/cicp/about/index.html>or call 1-855-266-2427.

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

[THIS SECTION MUST SPECIFICALLY INCLUDE THE POTENTIALLY BEST OUTCOME OF THE TREATMENT]

**5.3 What is the most likely outcome of being treated with this device?**

[THIS DESCRIPTION SHOULD BE BASED ON THE PHYSICIAN’S KNOWLEDGE OF THE PROPOSED TREATMENT, IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT’S CONDITION.]

**5.4** If you begin curative treatment with this device, you may no longer be eligible for hospice care. You may be able to receive hospice care again after you have ended the treatment with device and meet hospice eligibility requirements.

**5.5** You are free to stop the using this device at any time, and your treatment with it is voluntary. Before stopping, you should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage. If you stop treatment before it is finished, there will be no penalty or loss of benefits to which you may otherwise be entitled. If you decide to stop treatment before it is finished, please tell one of the persons listed in Section 6 “Contact Information” (below).

### Contact Information

**6.1 Who can I contact about this treatment?**

Please contact the doctor listed below to:

* Obtain more information about the device
* Ask a question about the device
* Talk about treatment-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your other doctors)
* Stop the treatment before it is finished
* Express a concern

Doctor Overseeing Treatment:
Mailing Address:
Telephone:

You may also express a concern about this use of the investigational device by contacting the Institutional Review Board listed below:

Central Michigan University

<Address>
e-mail: .edu

If you are concerned about a possible violation of your privacy or concerned about use of an investigational device, you may contact the Central Michigan University \_\_\_\_\_\_ at \_\_\_\_\_\_.

*When you call or write about a concern, please provide as much information as possible, including the name of the doctor providing treatment with the device, the CMU IRB number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

### record of Information provided

**7.1 What documents will I receive?**

 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 Children’s Hospital of Michigan- Detroit Medical Center medical record.)*

 Other (specify):

### SIGNATURE

**Consent/Assent**

I understand the information printed on this form. I have discussed this device, its risks and potential benefits, and my other choices with [DOCTOR’S NAME]. I agree with [DOCTOR’S NAME] that approved and commonly used treatments for my [NAME OF CONDITION] are unlikely to be as helpful as (DEVICE NAME) and are unlikely to prolong my life. I understand [DRUG/DEVICE] is not yet FDA approved. My questions so far have been answered. I understand that if I have more questions or concerns, I may contact one of the people listed in Section 6 of this document. If [DEVICE] makes me sick or causes me injury, I understand that I or my estate will be responsible for the costs of treatment unless I and [COMPANY NAME], the manufacturer of this [DEVICE], agree otherwise through a contract. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued treatment.

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

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

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



For use only if required by sponsor:

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

ID Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*If patient is not able to give consent for use of this investigational agent, use the section on the next page to obtain permission from a legally authorized representative or a parent.*

**Legally Authorized Representative or Parent Permission**

I have reviewed the information printed on this form and in any other provided 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 HEALTHCARE PROVIDER RESPONSIBLE FOR CONSENTING PATIENT]. I agree with [DOCTOR’S NAME] that approved and commonly used treatments for [PATIENT’S NAME]’s condition are unlikely to be as helpful as [DEVICE] and are unlikely to prolong his/her life. If the [DEVICE] makes [PATIENT NAME] sick or causes [HIM/HER] injury, I understand that [PATIENT NAME]or [HIS/HER] estate will be responsible for the costs of treatment unless [HE/SHE] and [COMPANY NAME], the manufacturer of this device, agree otherwise through a contract. I understand it is not yet FDA approved. 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.

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

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

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Relationship to patient: Parent Spouse Child Sibling Legal guardian Other

*If “Other,” explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Reason patient is unable to consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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For use only if required by sponsor:

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

ID Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Attestation of a Witness**

*(The witness must at least 18 years of age and preferably neither a clinician nor a family member of the patient.)*

I confirm that [PATIENT’S NAME] and/or [HIS/HER] legally authorized representative(s) have been provided with information about this [DEVICE], its risks and potential benefits and patient’s other choices, and have discussed all this information with [DOCTOR’S NAME]. I have witnessed that [PATIENT’S NAME] and/or [HIS/HER] legally authorized representative(s) indicated that [HE/SHE/THEY] understood the investigational nature of the treatment with [DEVICE], including risks and benefits of its use.

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

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

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

**Physician or Designee**

I have provided this patient and/or his/her legally authorized representative(s) with information about this use of this investigational agent 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 investigational treatment, including risks and benefits of its use.

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

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

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

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