MEDICAL CENTER NAVICENT HEALTH

**CONSENT TO BE TREATED**

**WITH A HUMANITARIAN DEVICE**

*<Name of Device>*

**A Device approved by the FDA as a Humanitarian Use Device for** *<indication>*

(IRB approved Version \_\_\_\_\_\_\_\_\_\_\_\_\_)

**Why is this device being used?**

Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is offering a treatment to you with a device called *<Name of Device>*. The <*Name of Device>* has been approved by the FDA as a Humanitarian Use Device for the treatment of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The effectiveness of the device for your condition has not been tested, and neither Dr. \_\_\_\_\_\_\_\_\_\_ nor the manufacturer is doing research to test its effectiveness. The Food and Drug Administration (FDA) is allowing the manufacturer *<Name of marketing Company>* to market the device and is allowing doctors to use it under a Humanitarian Device Exemption. The FDA can allow Humanitarian Device Exemptions when a manufacturer chooses not to do research studies to test a product because the product would be used to treat no more than 8000 people a year.

Before giving the exemption, the FDA looked at the manufacturer information and decided that the likely risks of the device are reasonable compared with the possible benefits and compared to other treatments for conditions like your child. In addition, the proposed procedure and device usage has been reviewed by and approved for use by the Navicent Health Institutional Review Board in accordance to FDA regulations.

**What will happen if I agree to treatment with this device?**

*(This section typically mimics information provided in the patient information)*

The *<Name of Device>* Device consists of *<*Description of the actual Device>, and how it is used including a description of the procedure used to implant or use the device.

What side effects or risks can I expect?

*<Description of risks associated with the use of the device and any procedures associated with the deployment/use of the device.>*

Issues that could happen during the procedure include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. These may require additional procedures or replacement of parts of the device.

Issues that could happen while the device is in place include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Events that could occur after the procedure is over and the device has been removed may include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Are there benefits to being treated with this device?

The device may be of benefit to you but this cannot be guaranteed. There has been no research to determine whether the device has benefit.

What other choices do I have if I do not want to be treated with the device?

The choice to treat you with the *<Name of Device>*  is completely voluntary. If you decide to not to be treated with this device, it will not affect the quality of care you are entitled, your relationship with your physician, or Navicent Health. If you choose not to be treated with this device, your physician will discuss the other medical care options with you.

Will I be charged for this device?

Yes. You or your insurance will be responsible for the costs of the device and all related care. You are advised to check with your insurance to see if they will cover the costs of the device. If your insurance refuses to pay, you will be responsible for the cost of the device and your treatment.

Who can answer my questions?

The patient information packet you receive as part of this consent may answer many questions you may have.

If you have any comments, concerns, or complaints about your treatment, please feel free to talk with Dr. \_\_\_\_\_\_\_\_\_\_. He can be reached by calling (\_\_\_)\_\_\_-\_\_\_\_\_\_.

If you wish to ask questions about the device or your rights to someone other than the physician or if you wish to voice any problems or concerns you may have about the device, you may contact the Chair of the Institutional Review Board at 478-633-1440.

**CONSENT**

I have read the information contained on this consent form. I have received and read a copy of the manufacturer’s patient information booklet on the *<Name of Device>*. I have discussed the information and treatment options with Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I have had the opportunity to ask questions and my questions have been answered. I understand the risks with this treatment and consent to being treated with the *<Name of Device>* Humanitarian Use Device.

Print Name of Patient Signature of Legal Guardian Date and Time

**Joshua B. Glenn, MD, FACS, FAAP**

Print Physician’s Name Signature of Physician Date and Time

Print Name of Witness Signature of Witness Date and Time