**Responsible Physician:** [Name and the address of the Responsible Physician]

**Divisional/Departmental/Institutional affiliation:**

**Project Title:**

Name of patient: [Name] Age: [Age]

(*Note that if you are providing consent for your child or are the legal representative, surrogate or next-of-kin for the individual who is to receive this emergency treatment, “you” in this form refers to the individual receiving treatment.*)

**The purpose of this form is to explain your options for treatment with an investigational drug or device. Investigational means that the Food and Drug Administration (FDA) has not yet approved the drug or device. Although the safety and effectiveness of the drug or device are not yet proven through clinical trials, you will be given this drug or device to treat your condition. This type of use of an investigational drug or device is known as an**  Emergency Use/Expanded Access **.**

This consent form applies to the use of [name of drug or device].

You do not have to agree to this treatment. If we learn something new that may affect the risks or benefits of treatment or your decision to be treated, you will be told as soon as possible.

1. **What treatment is being offered?**

You are being told about this treatment because  . This [name of drug or device] has not received approval for use in treating your condition from the Food and Drug Administration (FDA). Research studies to see how safe and how well this [name of drug or device] treats diseases may be happening, but you are getting this to treat your condition.

1. **What will happen and how long will this treatment last?**

1. **What will it cost?**

[The [name of drug or device] will be provided free of charge to you.]

*or*

[The cost of [name of drug or device] is .]

Your insurance plan may or may not pay for treatment with this [name of drug or device]. If your insurance plan does not pay for this treatment, you will be billed for the cost of the [name of drug or device] and all related doctor and hospital costs. The total of these charges depends on your specific treatment needs but the average cost of this type of treatment is $ .

1. **What side effects and risks can I expect?**

1. **Are there any other risks?**

Because this treatment is considered investigational and has not received FDA approval, there may be risks that we do not know about at this time.

1. **Who will pay for medical care if I am injured because of this treatment?**

If you are injured while being treated on this expanded access program, seek treatment and contact the doctor as soon as you are able. Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of injuries related to participation in expanded access programs. If you are injured as a result of your participation in this expanded access program, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

1. **How might this treatment help me?**

1. **What other options do I have?**

1. **Could my doctor decide not to offer me this treatment?**

1. **What will happen if I decide to stop treatment?**

If you decide to stop treatment, you should tell your doctor. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

1. **What if I have questions? Who can I call if I am injured?**

If you have any questions about this treatment or you feel you have an injury related to your treatment, please feel free to contact [Name and the address of the Responsible Physician] at [phone number]. If you cannot reach the doctor or staff, please page the doctor at [pager number].

For additional information about giving consent, or if you would like to talk with someone other than the researchers to discuss problems, concerns, and questions, offer input, discuss situations in the event that a member of the research team is not available, or discuss your rights as a patient receiving Emergency Use/Expanded Access treatment, you may contact the Yale University Institutional Review Board at (203) 785-4688 or at [hrpp@yale.edu](mailto:hrpp@yale.edu).

1. **Confidentiality:**

All efforts, within reason, will be made to keep your health information private.

Because your treatment involves the use of an investigation drug or device, Dr. [Name and the address of the Responsible Physician] and his/her team may share information about your specify as appropriate , as well as portions of your medical record, with the federal government’s Office of Human Research Protections, the Yale University Human Research Protection Program, the Food and Drug Administration and [drug or device manufacturer]. INSERT IF APPLICABLE: The device you will receive has a serial number which will become linked to your name. Yale, Dr. [Name and the address of the Responsible Physician] and his/her staff and the [drug or device manufacturer] will keep your health information in strict confidence and will comply with any and all laws regarding the privacy of such information.

1. **HIPAA Authorization for Access and Use of Protected Health Information:**

The health-related information that we gather about you is personal. The physicians are required by law to protect the privacy of information known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this expanded access program and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected if any of the recipients listed above are not required to comply with the HIPAA Privacy regulation.

By agreeing to participate in this expanded access program, you authorize the use and/or disclosure of the information described above for the purpose of monitoring the safety of investigational drug or device. This authorization to use and disclose your health information collected during your participation in this expanded access program will never expire. However, you may withdraw or take away your permission at any time except to the extent we have already released your information. You may withdraw your permission by telling the Responsible Physician or by writing to [Name and the address of the Responsible Physician] at the Yale University, New Haven, CT 06520. If you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

If you decide not to sign this form, it will not affect your other treatment options, payment or enrollment in any health plans or affect your ability to get benefits, however we would not be able to provide treatment to you with this investigational drug or device. You will get a copy of this form after it is signed.

# STATEMENT BY PERSON AGREEING TO TREATMENT

**I have read this consent form and the treatment plan has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to receive the treatment described above.**

Date Signature of patient or the patient’s parent

or legal representative/surrogate/next-of-kin

Consent obtained by:

Date Signature

Printed Name and Title