

**Yale University School of Medicine  
Yale-New Haven Hospital  
Informed Consent Document for Emergency Use Investigational Drug or Device**

**Responsible Physician:**

**Divisional/Departmental/Institutional affiliation:**

**Project Title:**

Name of patient: \_\_\_\_\_ 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.**

This consent form applies to the use of

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 [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 [drug or device] treats diseases may be happening, but you are getting this to treat your condition.

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

**3. What will it cost?**

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

or

[The cost of \_\_\_\_\_ is \_\_\_\_\_.]

Your insurance plan may or may not pay for treatment with this [drug or device]. If your insurance plan does not pay for this treatment, you will be billed for the cost of the [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 \$ \_\_\_\_\_.

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

**5. 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.

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

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

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

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

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

If you decide to stop treatment, you should tell your doctor.

**11. 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 **(INSERT NAME OF RESPONSIBLE PHYSICIAN)** at **(PHONE NUMBER)**. If you cannot reach the doctor or staff, please page the doctor at **(INSERT RESPONSIBLE PHYSICIAN'S 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 research subject receiving Emergency Use treatment, you may contact the Yale School of Medicine Human Investigation Committee at (203) 785-4688 or at [ysmhic@yale.edu](mailto:ysmhic@yale.edu).

**13. 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. **[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 School of Medicine Human Investigation Committee, 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. **[Responsible Physician]**

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and [his/her] staff and the [drug or device company] will keep your health information in strict confidence and will comply with any and all laws regarding the privacy of such information.

**If you decide not to receive treatment with this [drug or device], it will not affect your other treatment options, payment or enrollment in any health plans or affect your ability to get benefits. 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