The University of Texas Southwestern Medical Center

**Consent to Undergo Emergency Treatment with**

**Investigational Drug/Biologic/Device**

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| --- | --- | --- |
| Name of Device/Drug/Biologic: | | |
| Manufacturer: | | |
| Physician Name: | Telephone No.  (regular office hours) | Telephone No.  (other times) |

Name of Patient:

You have been informed that treatment of your disease or condition by standard, conventional methods is not/no longer effective. By signing this form, you consent to receive an investigational treatment that is not approved by the Food and Drug Administration (FDA). Although your physician believes this is the best option for you, no guarantees can be made when using investigational treatments.

You have also been informed that although this treatment is experimental, you are not a subject in a research study. Your doctor will release safety information about this investigational treatment to the manufacturer/supplier of the investigational test article and to the FDA.

**DESCRIPTION:** [insert the name of the investigational agent and describe its uses. Provide information on why the patient is a candidate for the use of the investigational agent].

**POSSIBLE RISKS:** [provide information describing the possible risks, side effects and/or adverse events associated with the investigational agent and its proposed use].

When using investigational treatments, it is not possible to know all potential risks and side effects. I have been informed that this treatment may involve risks or side effects other than those listed above.

**POSSIBLE BENEFITS:** [provide information regarding the benefits associated with the use of the investigational agent].

**ALTERNATIVE TREATMENTS:** I have been informed that I may refuse to receive this investigational treatment or may have it stopped at any time. The doctor may also stop its use if she/he feels it is in my best interest to do so. If I do not agree to this treatment or if the treatment is stopped early, the following alternatives are available to me: [describe alternative treatments that may be available to patients].

**ESTIMATED COSTS:** [provide the estimated costs to the patient for the investigational treatment].

**YOU WILL HAVE A COPY OF THIS CONSENT FORM TO KEEP.**

Your signature below certifies the following:

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| --- | --- | --- |
| • |  | You have read (or been read) the information provided above. |
| • |  | You have received answers to all of your questions. |
| • |  | You have received and read the manufacturer’s information about this device. |
| • |  | You have freely decided to allow your doctor to use this investigational treatment in your care. |
| • |  | You understand that you are not giving up any of your legal rights. |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Patient’s Name (printed) |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Patient’s Signature |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date / Time: AM-PM |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Legally authorized representative’s name (printed) |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Legally authorized representative’s Signature |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date / Time: AM-PM |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name (printed) of person obtaining Consent |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of person obtaining consent |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date / Time: AM-PM |