|  |  |
| --- | --- |
| NYU Langone Health  |  Institutional Review BoardHuman Research Protection1 Park Avenue | 6th Floor | New York, NY 10016 |

**[Instructions are included in parentheses and are bolded. Please delete all instructions prior to using the consent form. Changes to the form should only be made in the sections indicated.]**

## IND/IDE/HUD EMERGENCY USE CONSENT FORM

Physician Name:       Dept:

Phone:       Fax:

### E Mail:

### Name of investigational drug/biologic/device:

Your consent is requested to use the above-named product in:

[ ]  Your care

[ ]  The care of your child

[ ]  The care of someone for whom you are the legal representative. (Please note: for the inclusion of an Adult who requires the signature of a Legal Authorized Representative, IRB approval is required.)

Patient at the following NYU Langone Health Facility:

[ ]  NYU Langone Health (Tisch Hospital; Rusk Rehabilitation);

[ ]  NYC Health + Hospitals/Bellevue;

[ ]  NYU Langone Orthopedic Hospital;

[ ]  NYU College of Dentistry;

[ ]  VA NY Harbor Healthcare System.

This product has not been approved by the U.S. Food and Drug Administration (FDA). You are agreeing to the emergency use of (insert name of product/drug). The purposes of the emergency use of this drug/device are **(explain what the drug/product is and what is being evaluated)**.If you agree to the use of this product, this is what we will do: **(Include in this information: (1)what information will be collected for the emergency use; (2)the drug/device/product is being evaluated for safety/efficacy, etc.; (3) the amount of time will be required of the patient to participate; (4) describe all follow-up procedures, if applicable and include all procedures that will be completed and for how long).**

**If using a Humanitarian Use Device:** [This product has been approved by the U.S. Food and Drug Administration as a Humanitarian Use Device for the treatment of [**insert indication**]. The safety of this device has not been evaluated or demonstrated through research testing. The use of this device is not for research/testing evaluation purposes.]

If you agree to the use of this product, this is what we will do:

#### Risks:

The most likely risks of using this drug/biologic/device are:

There may be other significant or even life-threatening risks that we do not know about. (Provide any descriptions of increased risk if subject must be weaned off medication or any other information he/she should know before withdrawing. The subject should then be directed for further information in the section Alternatives.)

#### Benefits:

The possible benefits are:

#### Alternatives:

If you do not consent to the use of this product, the alternatives are:

**(Not participating in the emergency use also should be included as an alternative).**

If this emergency use involves medications or devices regulated by the U.S. Food and Drug Administration (FDA), the FDA and other regulatory agencies, the sponsor of the emergency use IND/IDE and NYU Langone Health staff working under the direction of the NYU Langone Health IRB may inspect records identifying you as a subject in this investigation.In addition, if your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The medical record is maintained by your treating physician or hospital, as applicable, and will be subject to New York State and federal laws and regulations concerning confidentiality of medical records. In addition, if you are a Bellevue patient, this form and your emergency use information will be available to Bellevue administration and their auditors.

#### Costs:

You or your insurance company will/will not [choose one or the other] be charged or held responsible for the costs of your care. Your individual insurance or government health insurance program may not cover certain services, items or procedures. You may want to discuss this with your insurance carrier in advance. You will be responsible for any co-payments and/or deductibles for services rendered"

1. If you are injured while you are in this emergency use, **(Provide an explanation as to whether compensation is available if an injury occurs(ed), and if available what it consists of or where further information can be obtained. Provide an explanation as to whether any medical treatments are available if injury occurs, and if so what it consists of or where further information can be obtained).**

If you decide not to participate, you will not be penalized or lose any benefits to which you are otherwise entitled. You can decide at any time to stop your participation without penalty or loss of benefits. **(Provide any descriptions of increased risk if** **subject must be weaned off medication or any other information he/she should know before withdrawing. This information should also be included in the Risks section of this consent form. Also, include any potential consequences if a participant decides to withdraw from the emergency use, if applicable.)** Your participation may be terminated by the Investigator if you are not complying with the emergency use requirements, it is in your best interest or the emergency use is stopped/terminated.

If you consent to this treatment and believe that you have suffered any injury as a result of this emergency use, you may contact Dr.      at      . The doctor will review the matter with you, identify resources that may be available to you, and provide information as to how to proceed for care. If you have any questions about the emergency use, or the drug/device or agent, please contact Dr.      at      .

This emergency treatment is not research and you will not be considered a research subject. Any data regarding your treatment will not be included in any report of the research activity. However, your privacy and confidentiality will be maintained/protected to the utmost ability of the research staff.

If you have any questions about your rights regarding the use of this drug or device in your medical care, you may contact the NYU Langone Health Institutional Review Board at 212-263-4110.

I have read the above explanations and have received answers to any questions I have about treatment with this product. I consent voluntarily to the emergency use of this drug/biologic/device.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_

Print Name of Participant Signature of Participant Date

**\*\*(Only include a signature line for a Legally Authorized Representative if you have received IRB approval for the enrollment of adults unable to consent.)**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_

Print Name of Person Signature of Person Date

Obtaining Consent Obtaining Consent