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|  | Institutional Review Board  Human Research Protection Program  1 Park Avenue | 6th Floor | New York, NY 10016  http://irb.med.nyu.edu |

**Expanded Access of IND/IDE CONSENT FORM**

Physician Name:       Department:

Phone:       Facsimile:

Instructions for using this template: Delete any RED text that is instructional and fill in and change to black any red text that provides optional language.

When you see [drug or device] referenced in this document, this indicates you need to replace the RED text with either the word drug or device.

**Purpose of the Consent Form:**

The purpose of this consent form is to explain your treatment options to you.

This treatment uses an investigational [drug or device] named fill in name of product.  Investigational means that the Food and Drug Administration (FDA) has not yet approved the [drug or device] for this use.  How well this investigational [drug or device] works or even if it is safe has not yet been proven through clinical trials.

You will be given this [drug or device] to treat your condition under a type of use known as Expanded Acces*s*. There are different types of expanded access uses. The type that will be used here is outlined below.

Your consent is requested to use the above-named [drug or device] in:

Your care

The care of your child

The care of someone for whom you are the legal representative

You are a patient at the following facility:

The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);

Bellevue Hospital Center;

Hospital for Joint Diseases Orthopedic Institute;

NYU College of Dentistry;

The New York Campus of the Veteran’s Affairs New York Harbor Healthcare System.

**The Expanded Access treatment being offered:**

The investigational [drug or device] is being offered to you through an Expanded Access program. This program is called, [Please pick what applies and delete the others]

Individual Patient including Emergency Use

Intermediate Size Population Use

Treatment IND

Treatment IDE

Compassionate Use IDE

Humanitarian Use Device (HUD)

**DELETE THIS NEXT SECTION IF NOT USING AN HUD**

***If using a Humanitarian Use Device:*** This product has been approved by the 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.]

**Details regarding the treatment being offered:**

You are being told about this treatment because Fill is reason     .

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.

You do not have to agree to this treatment and you can withdraw at any time. If you decide to stop the [drug or device] you need to know the following -----FILL IN AS APPRORIATE REGARDING SAFEGUARDS TO STOPPING

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.

If you agree to use this product, the following outlines what will be required of you:

LIST IN DETAIL USING NON-SCIENTIFIC TERMS WHAT WILL BE REQUIRED OF THE PATIENT. HOW MANY VISITS, WHAT TEST WILL DONE AND ANY INFORMATION REGARDING THE USE OF THE INVESTIGATIONAL PRODUCT

**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"

**Risks:**

Potential risks are: [Fill in. This information should be described according to frequency and anticipation of each type of risk. Those most likely to expect should be identified as such and listed first. Those least likely to be expected should be identified as such as listed next. Risks include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience, or breach of confidentiality.]

There may be other significant or even life-threatening risks that we do not know about.

**Benefits:**

The possible benefits are:

**Alternatives:**

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

**If you are injured:**

If you consent to this treatment and later believe that you have suffered any injury as a result of this emergency care, you may contact Dr.      at      .

This Hospital and any government agency or sponsor providing the device/drug will not provide special services, free care, or compensation for any injuries resulting from the use of this device. Treatment for such injuries will be provided under the same financial arrangements as those under which treatment is usually provided.

How your information will be protected:

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this treatment. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

**What information about me may be used or shared with others?**

The following information may be used or shared in connection with this treatment:

*[Edit the following as applicable: add or delete items as appropriate to your specific research protocol]*

* Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires and diaries.

*[Note: Genetic testing, HIV results, substance abuse treatment and mental health records may require different consents or language under applicable law.]*

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

**Why is my information being used?**

Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

**Who may use and share information about me?**

The following individuals may use, share or receive your information for this research study:

* The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
* The study sponsor: *[specify name(s) of study sponsors. Delete this item if an NYULMC department is the only study sponsor]*
* Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
* Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
* Other study sites
* *[Specify other non-NYU persons/entities as applicable, for example:*
* *Contract research organizations*
* *Central research laboratories*
* *Study related committees/boards/centers (Data & Safety Monitoring Board, Endpoint Committees, Clinical or Data Coordination Centers, etc.)*

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**How long may my information be used or shared?**

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

**Can I change my mind and withdraw permission to use or share my information?**

Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**Additional Information:**

This drug/device use is regulated by the Food and Drug Administration (FDA), the Office for Human Research Protection and other regulatory agencies, the sponsor of the study and NYUSM staff working under the direction of the IRB may inspect records identifying you as having received this [drug or device] for your condition**: FILL IN.**

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. FOR BELLEVUE ONLY ADD: In addition this form and your study information will be available to Bellevue Hospital administration and their auditors.

If you have a complaint that has not been resolved or you have questions regarding your rights regarding the use of this device in your medical care, please contact the NYU Langone Medical Center Institutional Review Board at 212-263-4110. They can review the matter with you, identify other resources that may be available to you, and provide information as to how to proceed.

This [drug or device] use will not be claimed as research and you will not be considered a research subject. Any data regarding your treatment will not be included in any report of a research activity.

If you have any questions about the [drug or device], please contact Dr.      at       .

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 use of this product.

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Print Name of Participant Signature of Participant Date

or Legal Representative\* or Legal Representative\*

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Print Name of Person Signature of Person Date

Obtaining Consent Obtaining Consent