**Expanded Access of Investigational New Drug (IND) or Investigational Device Exception (IDE) Consent Form**

**Instructions for using this template:**

If the study utilized expanded access of an investigational new drug or investigational device exception, complete this form as part of your submission to the IRB. This form documents the information required to ensure research is performed in accordance with the NYU Langone Human Research Protections Policy and Procedure Manual. This policy applies to all research involving human subjects if NYU Langone Health faculty, staff, students, or facilities are involved, regardless of sponsorship and/or performance site.

*[Remove the instructional text above prior to submitting the template]*

***BLUE TEXT***: *represents instructional language on the use of this document. Delete all instructions with Blue Text upon completion.*

***BLACK TEXT****:* *represents standardized text for the purpose of this form.*

***RED TEXT***: *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.*

|  |
| --- |
| Physician name:        |
| Department:        |
| Phone number:         |

**Key Information**

You are being invited to take part in an Expanded Access Protocol (EAP) to provide treatment for your condition with an investigational [drug or device]. Investigational means that drug has not been approved by the Food and Drug Administration (FDA). Your participation is voluntary which means you can choose whether or not you want to take part in this EAP treatment.

We are offering you treatment with an investigational [drug or device] through an EAP because you have a serious or life-threatening disease or condition, there are no comparable or satisfactory alternatives to treat your disease or condition, and you are unable to enroll in a clinical trial.

This treatment will last about *[# of days, months, years]* and will involve about *[# of visits].* While receiving this treatment your doctor will conduct routine tests and procedures to monitor your health*.*

**Foreseeable Risk and Benefits**

A comprehensive list of all possible risk and discomforts related to this investigational treatment is included below in the full consent, the most common risk experienced include *[insert the most foreseeable risk and discomforts reported or encountered as a result of participation].*

You maybenefit personally from receiving this investigational treatment.

Should you choose not to participate, the following alternatives are available to you: *[Insert and explanation of the alternatives to participation].*
For in-depth details regarding this Expanded Access Treatment, please refer to the full informed consent document below.

For questions and concerns regarding any of this information, contact *[insert study contact name, phone number and/or email address].*

**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 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

**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: Individual Patient including Emergency Use

**Details regarding the treatment being offered**

You are being told about this treatment because [fill in 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. DO NOT DESCRIBE RESEARCH PROCEDURES OR REQUIREMENTS FROM A CLINICAL TRIAL OF THE INVESTIGATIONAL DRUG/DEVICE]

**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 [list below]

**Alternatives**

If you do not consent to the use of this product, the alternatives are [list below]

**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.

**HIPAA Authorization**

Federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this EAP- in other words, for purposes of this treatment, including conducting and overseeing the EAP.

Your treatment outside of this EAP, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this EAP.

**What information may be used or shared with others in connection with this EAP?**

All information in your treatment record for this EAP may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the treatment team believes may be important to the EAP may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this EAP?**

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

* The treatment team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the EAP
* The study sponsor: *[specify name(s) of study sponsors. Delete this item if an NYU Langone Health department is the only study sponsor]*
* Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
* Health care providers, including your doctors and others who provide services to you in connection with this EAP, and laboratories or other individuals who analyze your health information in connection with this EAP.
* H+H personnel responsible for the support or oversight of the EAP at *[list Bellevue Hospital or other applicable H+H locations].*

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.

**What if I do not want to give permission to use and share my information for this EAP?**

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this EAP.

**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 for this EAP. 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 EAP.

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

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

**Additional Information**

This [drug or 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 NYUGSOM 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 [drug or 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 Patient Signature of Patient Date

or Parent/Guardian or Parent/Guardian

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Print Name of Person Signature of Person Date

Obtaining Consent Obtaining Consent

For adult patients unable to give consent, the consent for EAP treatment and authorization to collect and use protected health information is given by the following authorized patient representative:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Authorized Patient Representative (Print) |  | Signature of Authorized Patient Representative |  | Date |

Select the category that best describes the above Authorized Patient Representative:

[ ]  Court-appointed guardian

[ ]  Health care proxy

[ ]  Durable power of attorney

[ ]  Family member/next of kin; for this category describe relationship here:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_