***Note (REMOVE THIS TEXT BEFORE SUBMITTING):***

* *Note: this template can be used in paper form or made into an e-consent document.*
* *Grey boxes with black text in brackets are to be completed.*
* *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
* Orange text is optional, sample wording.
* *Do* ***NOT*** *delete the paragraph headings.*
* *This template is only to be used for HUDs.*
* *With the guidance language removed, this template has the following readability scores:*
	+ *Flesch Reading Ease: 66.2*
	+ *Flesch-Kincaid Grade Level: 7.6*

# **Consent for Humanitarian Use of Device**

**[Version date]**

*[If for Parental/Guardian Permission]:*

In this document, “I/my/you/your” mean your child [the child]. If your child turns 18 years old while receiving the treatment, your permission for him/her/them to continue receiving the treatment is no longer required. *[Minors should sign the adult consent at that time.]*

*[If use of an LAR]:*

In this document, “I/my/you/your” mean the participant you are giving permission to receive the treatment.

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the humanitarian use device (HUD) to you. Ask us any questions. You may also want to talk about it with your doctor and family, loved ones, or friends. The choice to receive the HUD, or not, is yours. If you decide to receive the HUD, please sign and date this form.

## What is a humanitarian use device?

A humanitarian use device, or HUD, is a device used to treat or diagnose less common diseases that affect small groups of people. Researchers cannot test a HUD in studies because fewer than 8,000 people have the condition it is used to treat. The Food and Drug Administration (FDA) has approved the use of HUDs for clinical treatment, even though they do not go through the same amount of testing that other medical devices do. The FDA believes that HUDs are likely to be safe and will likely benefit patients.

## Why am I being asked to receive a HUD?

You are asked to consider treatment with  [name of device]  because you have a rare condition and we believe  [name of device]  may help you. At this time, there is no other treatment we believe will be as helpful.

## Why is this device being recommended?

 [Include the name and nature of the device. Specify what the device is used to treat and describe what the device does.]

## What will I be asked to do?

You will complete the following tests and procedures:

 [List procedures and their frequency - you may use a table. Include whether a patient will be at home, in the hospital, or in an outpatient setting.]

 [Briefly label and describe any procedures that are part of standard care, including those that may be completed even if the patient does not agree to the treatment nor indicate consent for that procedure.]

 [Lastly, describe all procedures related to the treatment.]

## How long will I receive the treatment?

You will receive treatment for  [months/weeks, until a certain event] .

You can stop receiving the treatment at any time. If you decide to stop, we encourage you to talk to your doctor(s) first.

The doctors may stop the treatment at any time if they feel it is in your best interest, if you experience any severe side effects, of if you need more or other treatments.

**Do I have other choices?** You may choose not to receive the HUD. Standard treatments for  [name of condition]  include  [list standard treatments] . We are happy to talk to you about other treatment options.

## What are the risks?

 [Detail any known risk of harm that the participant may experience including physical, psychological, social, economic, legal, or unknown risks. Include likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent, and side effects that may be temporary, irreversible, long-term, or life-threatening. If appropriate, include measures to monitor risks.]

## What about pregnancy?

There could be serious harm to unborn children or children who are breast-feeding. You are asked to use a medically accepted method of birth control such as condoms if you engage in sex while you are receiving this HUD. If you or your partner do become pregnant while undergoing treatment with  [name of device] , you must tell your doctor and the doctor named below.

## Can this treatment help me?

We cannot and do not promise that this treatment will help you.  [Describe any anticipated benefit to the patient.]

## How will my information be used and protected?

 [Discuss steps that you will take to ensure confidentiality, e.g. where data will be stored, who will have access to the data, how will data be transferred, to whom and where, when will data be de-identified, security of storage, when and how data will be destroyed.]  We will take steps to protect all of your personal information, but we cannot promise confidentiality of all of your information. Treatment records will be kept according to legal requirements and will be a part of your medical record. If your information is published or presented at scientific meetings, your name and other personal information will not be used. You do not own any of the data collected and will not benefit financially if the data are used to create a new product or idea. Once within your medical record, others at WCM/New York Presbyterian Hospital (NYP) may have access to your information. The doctors for this treatment,  [company name for device] , the WCM Institutional Review Board (IRB), the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA) and/or their representatives, may access your records.

## Will I be paid?

You will not be paid.

## Do I have to receive the treatment? Can I quit the treatment?

It is your decision whether to receive the treatment or not. You have the right to choose not to receive the treatment or to stop your participation at any time. Your decision to receive the treatment or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, NYP, your doctors, or other employees. *[If applicable, discuss the process for participants to withdraw once the treatment has begun, including how participants can request their data not be stored, and state data already collected will remain in the medical record. Describe the process and option to continue with follow-up of their condition if applicable – how often and when this will end.]*

You will be told about new information that may affect your health, well-being, or willingness to participate.

## What are the costs?

If your insurance company will not pay for the procedure or the device, you will be responsible for these costs. If your insurance company will pay for only a portion of the procedure or the device, you will be responsible for the costs that insurance does not cover. Your treating physician or the medical team will contact your insurance company to see if they will pay for the device and any associated procedural costs.

## What happens if I am injured?

If you are injured from device, we will offer you care to treat your injuries. WCM may bill your insurance company or other third parties for the costs of the care. You may also be responsible for some of them.

There are no plans for WCM to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured because of the device, tell your doctor as soon as possible. The doctor’s name and phone number are listed below.

## What if I have questions or problems?

If you have any questions, problems, unexpected discomforts, concerns, complaints, or think that something unusual or unexpected is happening, please contact:

 [Physician's name]

 [Department]

 [Address]

 [Phone - this must be a 24-hour telephone number. On call number should be provided.]

 [Email address]

Be sure to tell the doctor about the treatment you have received.

If you have questions regarding your rights as a participant, about what you should do in case of any injury or illness because of your participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, irb@med.cornell.edu

Website: https://research.weill.cornell.edu/irb

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting http://www.hotline.cornell.edu/

# **HIPAA Authorization for Use and Disclosure of Your Protected Health Information**

We will be collecting health information about you and sharing it with others. This information is “protected” because it identifies you.

## Protected Health Information (PHI)

By signing this Consent Document, you are allowing the following people to use or release your protected health information:  [list all people or class of people (i.e. researchers and their staff) that will access PHI or you can also create a document to give participants that lists these people] .

This information may include:  [list PHI, e.g. results of physical exams, medical history, body mass index, sensitive diagnoses if applicable, etc.] . We will use this information to:  [include the purpose and describe each use of the requested information] . The researcher may use with and/or release the health information listed above to:  [name or class of persons involved] . We will also give this information to  [Company name] , which is the manufacturer of the device.  [Company name]  may be required to provide the following information to the FDA:  [list all relevant information] .

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the treatment and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

## Right to Withdraw Your Authorization

Your permission for the use and disclosure of your health information for this treatment shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed. However, you may stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office

1300 York Avenue, Box 303

New York, NY 10065

Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss them, please call (646) 962-6930.

Please note that the doctors involved in the treatment do not have to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your provider.

## Refusal to Sign

If you choose not to sign this consent form and permission for the use and disclosure of your PHI, you cannot receive the treatment. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, NYP, your doctors, or other employees.

## Signature

I have been told about the treatment, its purpose, procedures, benefits, and risks. I agree to receive the treatment and agree to immediately tell the doctor listed above if I experience any unexpected or unusual symptoms. My questions have been answered. I will get a signed copy of this form.

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Name of Adult Participant Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Parent/Guardian Signature of Parent/Guardian Date

**Legally Authorized Representative**

I am making a decision on behalf of the participant who signed above whether to receive the treatment. My questions have been answered. I will get a signed copy of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of legally authorized representative (LAR) or healthcare proxy |  | Print Name and relationship to participant (when appropriate) |  | Date |

**Witness to Consent of Participants Who Cannot Read or Write**

I confirm that the consent form was presented orally to the participant in the participant’s own language, the participant was given the opportunity to ask questions, and the participant has communicated consent to participate:

* Making his/her mark above
* Other means; Indicate here: \_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of witness for adults unable to read or write |  |  |  | Date |

#### **Participant Medical Record Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

#### **Physician Signature** (to be completed at time of informed consent)

I confirm that the treatment was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

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Name of Physician Signature of Physician Date