University of Pennsylvania

INFORMED Consent for Treatment

Humanitarian Use Device

**\*Please note: This is a template only. Please read the existing language carefully and revise as needed. Be sure to remove all blue text after including the appropriate information. Please fill in each section with the appropriate information pertaining to the patient and the device being used.\***

|  |  |
| --- | --- |
| **Protocol Title:**  | Humanitarian Use of <Insert Device Name> |
| **Physician:** | Insert Name of the Principal InvestigatorAddressInsert Phone Numbers |
| **Emergency Contact:** | Insert Emergency Contact Insert Phone Number/Pager, etc |

# Introduction

You are being offered the opportunity to be treated with <device name>, which is a humanitarian use device (HUD). A Humanitarian Use Device (HUD) is a medical device intended to benefit patients who have a disease or condition that affects no more than 8,000 individuals in the United States per year.

This device is used to <indicate the purpose, i.e., to treat or diagnose> and is approved for <indicate the approved indication>.

<Describe the device being used, why it may be appropriate for this patient, and how it is expected to work for the disease or condition.>

**The effectiveness of this device is not well-established.**

# What will be involved with the use of this device?

* Describe how the device will be used.
* Describe the procedures involved with use of the device (e.g., surgery)
* Be sure to include any (other) drugs and/or procedures that are required with the administration device, as applicable.
* Provide information pertaining to any safety tests or other assessments needed during the time that the patient receives the device

# How long will the treatment with the device be?

< Note how long the treatment or use of the device will be; Or incorporate a specific schedule for the receipt of the device, if one is known.>

# What are the possible risks, side effects and discomforts associated with the use of this device?

**LIKELY:**

* Provide appropriate risk listing

**LESS LIKELY:**

* Provide appropriate risk listing

**RARE, BUT SERIOUS:**

* Provide appropriate risk listing

## Reproductive risks

<Do not include reproductive risk information if it does not pertain to the patient being offered the device or limit the information as appropriate.>

Because of the effects of this < device >, 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 < detail required contraception >is you engage in sex while you are receiving this investigational < device >.

If your partner becomes pregnant while you are being treated with this < device >, you must tell the investigator and your partner should consult an obstetrician or maternal-fetal specialist.

## Unknown Side Effects

There may also be other unknown side effects that could harm you as a result of <insert name of device >. We cannot predict what these side effects may be, which is why it is so important for you to report any side affects you experience to your physician. There is always the possibility that you will have a reaction that, if not treated properly, could be life-threatening.

# What are the possible benefits associated with the use of this device?

< Describe the potential benefits of the device but also state clearly that the patient may have no benefit and that their condition could worsen.>

# What if new information becomes available?

We may find more information about the use of this device that could be important to you. This includes information that, once learned, might cause you to change your mind about using the device. We will notify you as soon as possible if such information becomes available.

# What alternative treatments or procedures are available?

<Describe any available alternatives instead of receiving this device.>

# Will my insurance provider or I be charged for the costs of this device or any procedure associated with its clinical use?

<Describe how the cost of the device and any related procedures will be covered.>

# What happens if I am injured or hurt as a result of this treatment protocol?

We will offer you the care needed to treat injuries resulting from taking the device. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania 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, tell your physician as soon as possible. The physician’s name and phone number are listed in this form at the top.

If you have a medical emergency you should go to the nearest emergency room. You may also contact your own doctor or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a treatment protocol at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

# Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. This treatment is being overseen by the Food and Drug Administration (FDA) and they may review your medical record.

# Electronic Medical Record and Release of Study Related Information

[This language is required for investigational treatment being conducted within Penn Medicine when data and results may be placed into the electronic medical record or are otherwise built in the EMR. As a reminder, studies must be built into the EMR/ PennChart if the study will be utilizing PennChart EMR ordering, billing or recruitment capabilities.]

## What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in this treatment that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your treatment. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from this treatment will be added to your existing medical record.

## What may be placed in the EMR?

Information related to your treatment (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to other appropriate Penn Medicine workforce members that are not part of the treatment team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

## Will I, as a subject, have access to information related to this treatment within the EMR/?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this treatment, you will have access to related information within your EMR through Penn Medicine’s patient portal – called MyPennMedicine (MPM).

# Who can I call with questions, complaints or if I’m concerned about my rights?

If you have questions, concerns or complaints about your participation in this treatment protocol, you should speak with the Physician listed on page one of this form. If the physician or physician’s team cannot be reached, or you want to talk to someone other than the treating physician, you may contact the Office of Regulatory Affairs with any concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

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| --- |
| When you sign this form, you are agreeing to participate in this treatment protocol. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to any appropriate outside organizations or people involved with the operations of this protocol. |

A copy of this consent form will be given to you. You will also be given the Penn Medicine Notice of Privacy Practices that contains more information about the privacy of your health information.

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Name of Patient **(Please Print)** Signature of Patient Date

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Name of Person Obtaining Signature Date

Consent **(Please Print)**

(Optional) Use the authorization line only for treatments which are approved by the IRB to use representatives to authorize the patient’s treatment. Delete if not applicable.

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

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Authorized subject Authorized subject Date

representative **[print]** representative **Signature**

Provide a brief description of above person authority to serve as the subject’s authorized representative.

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