Revised – June 1, 2022

Patient name:

DOB:

MRN:

Physician:

TEMPLATE: Treatment Use of an Investigational Drug/Device

***Instructions:***

*“Italicized red writing” provides instructions and guidance on how to complete this template; it should be removed from the final documents*. *This template is to be used when a physician wishes to treat a patient with a drug or device that is not yet FDA approved, or will be used off-label. It may be used for Emergency Use, Expanded Access/Treatment Protocols, Humanitarian Use Devices, and Compassionate Use of a Device. If you are unsure about the applicability of this template, contact* [*irbassist@spectrumhealth.org*](mailto:irbassist@spectrumhealth.org)*.*

“Black writing**”** *is required language to be included in final documents.*

# **Treatment Use of an Investigational Drug/Device**

**Name of the Device/Drug:** *(insert name)*

**Sponsor/Manufacturer:** *(insert the organization providing the drug/device)*

**Treating Physician:** *(insert name of Principal Investigator)*

**“You”** refers to the patient*(include if adult-only study)*

**“You”** refers to you and your child*(include if pediatric-only study)*

**“We”** refers to*(include organizations providing expanded access/compassionate use, for example, Spectrum Health or Spectrum Health Helen DeVos Children’s Hospital)*

**Invitation to Participate in the Treatment Use of an Investigational (Device/Drug)**

The purpose of this consent form is to explain a treatment option with *(name of the device/drug)*. The treatment with this *(Name of the device/drug)* is “investigational” because it does not yet have approval from the United States Food and Drug Administration (FDA) for medical use. The FDA will sometimes allow patients to receive an investigational treatment outside of a research study when there are no comparable or satisfactory therapies or alternative treatment options.

*Insert the following if this treatment involves a Humanitarian Use Device (HUD):*

*(Name of Device)* is a Humanitarian Use Device (HUD). A HUD is a device that researchers can’t test in studies, because no more than 8,000 people have the condition it’s used to treat. The U.S. Food and Drug Administration (FDA) has approved the use of HUDs for the clinical treatment of patients, even though HUDs do not go through the same amount of testing that other products do. The FDA believes that HUDs are likely to be safe and will probably benefit patients.

***Why is my doctor suggesting this treatment?***

Your doctor has determined that this treatment may be of benefit for you. Usually, patients can only receive an investigational product by taking part in a research study. However, this option is not available to you because *(explain why the patient cannot be a part of a regular clinical trial)*.

If you agree to this treatment, *(name of the device/drug)* will be made available to you by your doctor and may be used as part of your medical care. It is important that you understand that this *(device/drug)* may not benefit you and could lead to poor results such as illness, injury, or death.

## ***What should I know about this treatment?***

* Your doctor will explain this treatment to you
* Because *(device/drug)* is not approved by the Food and Drug Administration (FDA) to treat your condition, the use of it to treat you is therefore investigational and experimental.
* Whether or not you agree to receive this treatment is up to you.
* You can agree to take part now and later change your mind.
* Whatever you decide your choice will not be held against you.
* You can ask any questions you want before you decide whether or not you will agree to this treatment.

## ***What happens if I say yes to this treatment?***

Provide detailed information for all related treatment(s)/procedure(s), for example, “You will receive (x) infusion over (x) weeks or the device will be implanted via surgery, etc. Describe all monitoring procedures that will take place such as lab tests or imaging, or additional clinic visits that may be required.

The physician is responsible to track and record all adverse events. Data cannot be collected that will be used to support research studies or other data submitted to the FDA in support of an IND, PMA, etc.

Please insert the required language verbatim: In addition to this above monitoring and procedures for treatment, your treating doctor (or drug/device manufacturer/Sponsor – whomever holds the IND/IDE) will report any adverse events, side effects or outcomes to the FDA.

What are the possible risks or side effects of the treatment?

*List known or reasonably anticipated risks, discomforts, inconveniences or side effects and what measures will be taken to minimize or treat them, and/or a statement that risks cannot be predicted.*

The risks of this treatment are (List and define all physical, psychological, privacy, legal, and social risks of the treatment)

In addition to the risks listed above, there may be risks or side effects that are unknown.

*If blood will be collected during this treatment include:* Under Michigan Law, an HIV and Hepatitis test may be done on you without your consent if a healthcare worker is exposed to your blood or other body fluids. If the results of an HIV or hepatitis test indicate that you are HIV or hepatitis positive, you will be told about these test results and given information about the disease, treatment resources and other options.

***Are there benefits from this treatment?***

We cannot promise any benefits to you from being treated with *(name of the device/drug)*. Your condition may get better, stay the same, or worsen.

***What other options are there?***

Your doctor will discuss other treatment options with you, which may include doing nothing. You may choose not to accept this experimental treatment and it will not be held against you. A refusal will not lead to any penalty or loss of benefits to which you are otherwise entitled.

***Will I need to pay for any of the tests or procedures?***

*Describe ALL costs to the patient from receiving this investigational drug or device*. Explain if the device/device will be provided by the sponsor.

***What if I am injured or made sick from this treatment?***

If you are injured or made sick as a result of this treatment, medical care will be provided to you. Please talk to your doctor for more information. However, neither the sponsor *(device/drug manufacturer)* nor Spectrum Health has any funds set aside for financial compensation for injuries or illnesses you may experience as a result of this treatment, or for any costs of medically treating those injuries or illnesses. Therefore, medical care for any illness or injury related to this treatment will be billed to you and/or your insurance.

***What information will be collected about me during the treatment?***

*Describe what medical information will be collected during the treatment and where this will be obtained from, for example: what will be collected from the medical chart or phone calls to check on the health of the patient. Indicate where this information will be stored and how it will be secured. State the purpose for the collection of this information.*

***Who will have access to my private information?***

We will collect, use, and share your information including (list all data that will be collected, used, and shared such as name, date of birth, contact information, social security number, medical record number, insurance information, existing medical records and medical history, new health information) collected for the purposes of this treatment.

Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information. We cannot promise complete confidentiality.

Organizations that may inspect (look at) and copy your information for quality assurance and data analysis include:

* The treating physician and medical staff
* Spectrum Health staff or its agents
* Spectrum Health Institutional Review Board
* Spectrum Health offices that have the responsibility to oversee patient care and investigational drugs and devices
* Food and Drug Administration (FDA)
* The manufacturer of the medical device, drug or its agents (monitors, auditors)
* Agencies that accredit the hospital or other programs

Some of these organizations may be given direct access to your medical records for verification of the investigational procedures/data involved. By signing this document, you are authorizing this access.

***Who can I talk to?***

If you have questions or concerns about the use of this *(device/drug)*, talk to your treating physician or other members of the staff at *Insert contact information of the PI and an alternate number for the team)*

You can also contact the Spectrum Health IRB office at (616) 486-2031 or [irbassist@spectrumhealth.org](mailto:irbassist@spectrumhealth.org) for any of the following:

* Your questions, concerns, or complaints are not being answered by the treating physician or staff.
* You cannot reach the treating physician or staff.
* You want to talk to someone besides the treating physician or staff.
* You have questions about your rights.
* You think that you may have been harmed by the treatment.

You may also contact our anonymous hotline at: (855) 613-2262 or (616) 391-2624.

|  |  |  |
| --- | --- | --- |
| ***\*\*\*\*INFORMATION REGARDING SIGNATURE PAGE\*\*\*\****  ***There are five signature block examples attached to this template consent. Adapt the signature page for this treatment based on the study population. Delete the signature blocks that are not applicable.***  ***For example: Omit the signature block regarding children (i.e. do not include parent/guardian signature line(s) if you do not plan to enroll children in this treatment.***  **Signature Block for Capable Adult: Long Form** | | |
| Your signature below documents your permission to be treated with *(name of the device/drug)* and to use or share your personal information.You will receive a signed copy of this complete form. | | | |
|  |  |  | |
| Signature of Patient |  | Date | |
|  |  | | |
| Printed name of Patient |
|  |  |  | |
| Signature of person obtaining consent |  | Date | |
|  |  |  | |
| Printed name of person obtaining consent |  |  | |

***The following signature block is to be used when an impartial witness is needed for non-readers or visually impaired patient***

|  |  |  |
| --- | --- | --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the patient. I witnessed that all of the patient’s questions were addressed. I witnessed the patient freely giving consent to participate in this treatment. | | |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  | |
| Printed name of Impartial Witness |

***The following signature block is to be used when an adult participant is unable to sign their name and date the informed consent form. A witness is required to verify that the participant provided their “mark”.***

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| I witnessed the participant providing their “mark” on the above signature line and have identified the participant by documenting his/her name on the above “Printed name of patient” line.   |  |  |  | | --- | --- | --- | |  |  |  | | Signature of Impartial Witness |  | Date | |  |  | |   Printed name of Impartial Witness |

**Signature Block for Adult Unable to Consent**

|  |  |  |
| --- | --- | --- |
| Your signature below documents your permission to be treated with *(name of the device/drug)* and to use or share your personal information.You will receive a signed copy of this complete form. | | |
|  |  |  |
| Printed name of patient |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |  |
| Printed name of legally authorized representative |  | Relationship to participant |
|  |  |  |
| Signature of person obtaining consent and assent  **(Remove latter section if assent will not be obtained)** |  | Date |
|  |  |  |
| Printed name of person obtaining consent and assent  **(Remove latter section if assent will not be obtained)** |  |  |

***Add the following block if you will document verbal assent of the participant on this consent form. If you will be documenting written assent add an assent signature line, printed name line and date line to the consent form or have a separate assent form.***

|  |  |
| --- | --- |
| Assent | * Verbal Assent Obtained * Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted. |

***[The following signature block will be completed if an impartial witness is required for LAR that is a non-reader]***

|  |  |  |
| --- | --- | --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant. I witnessed that all of the patient’s questions were addressed. I witnessed the patient freely giving consent to participate in this treatment. | | |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  | |
| Printed name of Impartial Witness |

**Signature Block for Children**

Your signature below documents your permission for the child named below to be treated with (*name of the device/drug)* and to use or share your personal information.You will receive a signed copy of this completed form.

|  |  |  |
| --- | --- | --- |
|  |  | |
| Printed name of child |
|  |  |  |
| Signature of parent or guardian |  | Date |
|  | * Parent * Guardian (See note below) | |
| Printed name of parent or guardian |
| **Note on permission by guardians:** An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child’s general medical care. Attach the documentation to the signed document. | | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

**Signature Block for Limited English Speaking: Short Form**

|  |  |  |
| --- | --- | --- |
| This English version of the Informed Consent Form is to accompany the Short Form you sign in your stated primary language. You will receive a signed copy of this complete English Informed Consent Form and Short Form together. | | |
|  |  | |
| Printed name of participant |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

|  |  |  |
| --- | --- | --- |
| I declare that, to the best of my ability, I have accurately interpreted to/from the participant’s stated primary language, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Specify language), everything said during the informed consent discussion. | | |
|  |  |  |
| Signature of Appointed Medical Interpreter |  | Date |
|  |  |  |

Printed name of Appointed Medical Interpreter Time

|  |  |  |
| --- | --- | --- |
| I declare that I was present for the entire informed consent discussion and that, to the best of my ability, everything said during the discussion was accurately interpreted by the Spectrum Health-appointed interpreter to/from participant’s stated primary language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Specify language). | | |
|  |  |  |
| Signature of Witness to Informed Consent Interpretation |  | Date |
|  |  |  |
| Printed name of Witness to Informed Consent Interpretation |  | Time |