*This template (Emergency Use) is for treatment uses involving investigational drugs/devices/biologics for the treatment of patients not in a clinical trial. This template is to be used for the treatment of patients in a life-threatening situation where prior IRB review and approval is not feasible.*

*Additional modules for special cases can be found on the IRB website.   
These modules can be inserted into the appropriate study-specific text boxes.*

**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type. Instructions are in gray boxes and should be deleted in final consent.

IRB-required template language is in black type and should not be changed.

Rarely, changes to the required language may be necessary. To petition for a change in required language, submit proposed changes with justification on the “ICF Template Change Form” to the IRB office.

Sample language, which can be used, modified, or deleted as appropriate for your study, is in blue type. Please maintain the blue color to distinguish your study-specific information from the required template language.

* Arrows are used to show alternative choices. In the final consent, arrows can be deleted and the usual margin maintained.

**Medical College of Wisconsin and Froedtert Hospital/Children’s Wisconsin**

**INTRODUCTION TO THE INFORMED CONSENT**

Name of Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<Treating Physician>

<Department>

<Telephone Number>

<Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226>

//

<Children’s Wisconsin

8915 W Connell CtMilwaukee WI 53226>

For your medical care, <physician> would like to use a <drug/device/biologic> that has not been approved as “safe and effective” by the FDA (or, <by the FDA for this purpose>). This form tells you why this treatment is being offered, what will happen during the treatment, possible risks and benefits to you, your choices, and other important information. If there is anything that you

do not understand, please ask questions. Then you can decide if you want to receive this treatment or not.

***Insert the following language if this Emergency Use is intended for a minor.***

Patient: If you are under the age of 18, your parent or guardian needs to give their permission for you. Parent/Guardian: The word “you” in this form refers to your child.

INTRODUCTION – WHY ARE YOU BEING OFFERED THIS TREATMENT?

***Describe reason(s) for subject participation, such as diagnosis and eligibility, and a brief description of the key intervention.***

You are being offered this treatment because you have a serious condition, <name condition>. We believe that <name of investigational drug/device/biologic> may help you. Your treating physician thinks this <investigational drug/device/biologic> may be the best option for your clinical care.

<Name of investigational drug/device/biologic> is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it’s safe and effective. Because this <drug/device/biologic> is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use.

<Sponsor>, a drug company, is funding the study. **OR** The National Institute of Health, a government agency, **OR** the American Heart Association is funding this study.

***If a financial conflict of interest needs to be explained, state it here.***

DO I HAVE TO RECEIVE THIS TREATMENT?

You can decide whether to receive this treatment or not. You are free to say yes or no. If you say no, your physician will continue to provide regular medical care. Even if you decide to receive this treatment, you may choose to stop at any time.

Receiving treatment with an <investigational drug/device/biologic> is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the procedures, tests and visits follow a set plan that must be kept.

WHY IS THIS <DRUG/DEVICE/BIOLOGIC> BEING RECOMMENDED?

<Name of investigational drug/device/biologic> is used to treat <name of condition> by <describe what the drug/device/biologic does>. e.g. “connecting the two chambers of the heart for better blood flow.”

WHAT WILL HAPPEN IF I RECEIVE THIS TREATMENT?

***Provide a concise overall summary of the procedures.***

* ***Begin with screening procedures, if applicable.***
* ***Use lay language and explain the purpose of the procedure if it is unfamiliar.***
* ***Include the duration of each visit or procedure.***
* ***Emphasize drugs/procedures that are investigational, compared to routine care.***
* ***State if any procedure is experimental.***
* ***An attachment may be added [Attachment #1, optional] with details of the treatment schedule and procedures.***

**Screening procedures:**

***If the treatment requires screening procedures, briefly describe; otherwise delete.***

If you decide to receive the treatment, some screening tests will be done first to see if it is safe to receive treatment with this <investigational drug/device/biologic>. [Describe screening procedures].

If the screening information shows that you meet the requirements, then you will be able to start the treatment. If the screening information shows that you cannot receive the treatment, the treating doctors will discuss other options with you and/or refer you back to your regular doctor.

**Summary of Treatment Activities:**

***Provide a summary of*** ***activities and/or follow-up related to the treatment***

HOW LONG WILL I RECEIVE THE TREATMENT?

***Choose one or more options and modify regarding the patient’s involvement:***

* You will receive the treatment for about [estimated length of time of patient’s involvement]..
* You will take the [drug/intervention] for \_\_\_\_ months/ weeks.
* After the [drug/intervention] is finished, we want to keep in touch with you to follow your health over time. We will telephone you / ask you to come in to the clinic [once a month, once a year] [for the next year / for the rest of your life] and ask about ….

CAN I STOP RECEIVING THE TREATMENT?

***Choose one or more of these options and modify:***

You are free to stop the treatment at any time. If you stop, your regular medical care will not change. If you are thinking about stopping the treatment, please tell the doctor.

* The doctor can tell you about the effects of stopping, and you and the doctor can talk about what follow-up care would help you the most.
* You might be asked to come back for one more visit to check your health.
* You might be asked to return your research drug containers.

The doctor may take you off this treatment at any time. This would happen if:

* They think it is in your best interest.
* The <investigational drug/device/biologic> is no longer available.

If this happens, the doctor will tell you.

ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM RECEIVIING THE TREATMENT?

***Include only if applicable to the treatment.***

[You should not take aspirin while taking this drug.]

WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE TREATMENT?

There are risks to taking part in any treatment involving an investigational [drug/device/biologic]. There is a risk that you may get [a drug/drug combination/device/intervention/dose of a drug] that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from [drug] itself, or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

**You need to tell the doctor immediately if you experience any problems, side effects, or changes in your health.** If you have \_\_\_\_ [severe bleeding], call Dr. \_\_\_ immediately at \_\_\_\_\_. In an emergency, call \_\_\_\_.

RISKS OF *\_\_\_\_\_\_\_ [THE INVESTIGATIONAL DRUG/DEVICE/BIOLOGIC]*

Treatment of your condition with the <investigational drug/device/biologic> may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Many go away soon after you stop taking the [drug/device /intervention]. Drugs can affect individuals in different ways. . Complications of some of the side effects below may lead to life-threatening events such as …. (infections, kidney failure, bleeding, and possibly death).

The side effects that other people have experienced so far with the [drug/device /intervention] are:

***State here the risks related to the intervention(s) itself.***

* ***Risks can be described as a bulleted list or table, using lay language.***
* ***Begin with the most common, and include the probabilities or commonality of each side effect.***

***Device risks:*** *In addition to risks of the device itself, including possible malfunction and its consequences, also address the following long-term risks, such as: risks of removal, consequences of removal, device maintenance, and who will bear the cost of maintenance and/or removal.*

OTHER RISKS OF THIS TREATMENT

***Here list other study procedures and their risks, such as***

* ***to assess study eligibility,***
* ***more frequent assessments for safety or for disease progression,***
* ***other required medications, etc.***

**Other procedures [and medications] that are part of the treatment also involve some risks:**

*Only include reproductive risk information if it pertains to the patient being offered the investigational drug or limit the information as appropriate.*

**Reproductive risks:** Because of the effects of this drug/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 condoms if you engage in sex while you are receiving this investigational treatment. If your partner does become pregnant while you are on this treatment you must tell the doctor and consult an obstetrician or maternal-fetal specialist.

ARE THERE ANY COSTS TO RECEIVING THIS TREATMENT?

**The following language should be used if Emergency Use is occurring at MCW, Froedtert Hospital, or Versiti.**

***Outline clearly:***

* ***Activities/financial costs that are part of routine care and to be billed to subject/ subject’s insurance company***
* ***Activities/costs that are part of the research study and to be paid by sponsor/Investigator***
* ***Froedtert Hospital cannot be identified as a funding source unless approved through the Office of Clinical Research and Innovative Care Compliance***
* The **investigational** <**drug/device**/biologic> will be paid for by **the** <sponsor>. All other medical care will be billed to you or **your insurance** carrier. Some insurers will not **pay** for drugs, tests or hospitalization that are associated with investigational products, so check with your insurer before you receive this treatment. You will be responsible for all costs not covered by your insurance. If you have questions regarding costs, please contact Dr. \_\_\_\_.

**The following language should be used if Emergency Use is occurring at Children’s Wisconsin.**

You and/or your health insurance may be billed for the costs of medical care while you are receiving treatment with <insert name of the investigational drug/device>, if these expenses would have happened even if you were not receiving the drug, or if your insurance agrees in advance to pay.

Include information about whether the manufacturer is supplying the agent and/or will be covering the cost of the investigational drug/device.

WILL I BE GIVEN NEW INFORMATION ABOUT THE TREATMENT?

If we learn any important new information [about the drug/device/intervention] that might change your mind about receiving this treatment, we will tell you about it right away. You can then decide if you want to continue the treatment.

WHO CAN I CALL WITH QUESTIONS ABOUT THE TREATMENT, COMPLAINTS, OR IF I AM CONCERNED ABOUT MY RIGHTS?

* If you have more questions about the treatment with this <investigational drug/device/biologic> at any time, you can call <doctor> at <Telephone number>.
* << If you have questions about your rights, any concerns, or complaints, please contact the Children’s Wisconsin Human Research Protection Program at 414-337-7705.>>
* << If you have questions about your rights as a patient receiving this investigational treatment, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.>>

**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. If your information is published or presented at scientific meetings, your name and other personal information will not be used. Some organizations that may inspect and/or copy your records include groups such as:

*List relevant agencies*

* Food and Drug Administration
* The Manufacturer [include name]
* Institutional Review Board of Record
* The Medical College of Wisconsin
* Children’s Wisconsin
* Other persons or entities as appropriate

**CONSENT TO RECEIVE THE TREATMENT**

**By signing my name below, I confirm the following:**

* I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
* The treatment’s purpose, procedures, risks and possible benefits have been explained to me.
* I voluntarily agree to receive the treatment. I agree to follow the procedures as directed. I have been told that I can stop at any time. [This text should be revised for projects where the intervention is implanted and cannot be removed]

**IMPORTANT:** You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

***Signature line instructions: Generally, the patient or parent’s signature is sufficient. If the patient is a minor delete the signature lines for adult patient.***

***Date or Date & Time: Time is optional to include; if included, must be completed by each signer.***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Adult Patient’s Name** *please print* | **Adult Patient’s Signature** | **Date** OR **Date**/**Time** |
|  |  |  |
| **Name of Parent/Guardian or Legally Authorized Representative** (if applicable**)**  *please print* | **Signature of Parent/Guardian or Legally Authorized Representative** | **Date** |
|  |  |  |
| **Name of Patient** *(please print)* | **Relationship to Patient** *(e.g. Court-appointed guardian, health care power of attorney, next of kin, etc.)* | **Date** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of treating physician** *please print* | **Signature of treating physician** | **Date** |