*This template (Expanded Access/Treatment 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 a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.*

*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/Children’s Wisconsin**

**INTRODUCTION TO THE INFORMED CONSENT**

<Expanded Access Title>

<Principal Investigator>

<Department>

<Telephone Number>

<<Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226>> //

<<Children’s Wisconsin

8915 W Connell Ct

Milwaukee WI 53226>>

For your medical care, <Doctor> 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 the patient this Expanded Access/Treatment Use is intended for is 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 treatment, 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 doctor 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.

***List any funding source for the project, including departmental or internal funding:***

The <doctor and/or [*Institution*]> will be paid by [*insert name*] for carrying out this project.

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

***For example:*** <Funding source> is funding this treatment. <PI name> receives financial support from <funding source.>

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 doctor 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 and there may be unknown risks as well; 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 subject’s involvement:***

* You will receive the treatment for about [estimated length of time of patient’s involvement]
* You will take the [drug] 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 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.***

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

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

There are risks to receiving 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 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 … (infection, 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 drug/device/biologic 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 (or indicate if it is not removable), device maintenance, and who will bear the cost of maintenance and/or removal.*

OTHER RISKS OF THIS TREATMENT

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

* ***to assess 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:

***Include section only if applicable to the project.***

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

***Include section only if applicable to the treatment and patient.***

REPRODUCTIVE RISKS

**Risks to subjects who could become pregnant**

We do not know if the [drug(s) / intervention] cause(s) harm to a baby, so we do not want anyone who might be pregnant to receive this treatment. // We know the [drug(s) / intervention] used in this treatment affect(s) babies, so we do not want anyone who might be pregnant to receive this treatment.

You should not become pregnant or nurse a baby while in this project. You must tell your doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the treatment/and during the treatment / and at the end of the treatment.

***Include section only if applicable to the project.***

You may not donate eggs during your participation in the treatment or for XX days/months after stopping the [drug/intervention].

***Include section only if applicable to the project.***

If you become pregnant while receiving the treatment, <you will be dropped from participation for safety reasons/the drug will be stopped for safety reasons>. If you become pregnant while you are taking this experimental drug [or within xx days after you have stopped taking it,] we ask that you inform your doctor immediately. Your doctor will ask you for written permission to obtain information from you or your obstetrician on your pregnancy and the health of the baby.

**Risks to a subject’s partner(s)**

***This risk does not need to be included unless there is evidence or concern that the drug causes paternity-related birth defects, or unless required by a Sponsor. Modify as needed.***

If you and your partner(s) are able to become pregnant, one or both of you must use some form of effective birth control, because [it is unknown if [drug/intervention] could affect a baby // we know that the [drug/intervention] affects babies.] You must tell your doctor right away if you think your partner is pregnant.

***Include section only if applicable to the project.***

You may not donate sperm while receiving this treatment or for XX days/months after stopping [drug/intervention].

***Include section only if applicable to the project.***

If you think you have gotten your partner pregnant while you are taking this experimental drug [or within xx days after you have stopped taking it], we ask that you inform your doctor immediately. At that time, your doctor will ask permission of your partner for the use and disclosure of health information regarding the pregnancy. Your partner will be asked to sign a separate consent form and can choose to do this or not. Your partner will be asked to sign this form to allow your doctor to contact your partner’s obstetrician to collect information on the progress of the pregnancy and its outcome. Your doctor will make this information available to the sponsor for safety monitoring.

**Birth control methods for all subjects**

***Insert this section if needed and modify list as needed. The list of birth control methods may be separated into methods required for subjects who could become pregnant and subjects whose partner could become pregnant.***

Check with your doctor about the birth control methods needed for this project and how long to use them. Some methods might not be good enough while receiving this treatment. If you are having sex that could lead to pregnancy, you should use [one form/two forms/one form of highly effective/ two forms of highly effective/etc.] birth control while you are receiving this treatment.

This may include:

* Not having vaginal sex (abstinence)
* Taking birth control pills orally
* Having birth control shots or patches such as Depo-Provera
* Surgical sterilization (hysterectomy/tubal ligation or vasectomy)
* Limiting sexual activity to a partner who has undergone surgical sterilization
* Use of an intrauterine device (IUD)
* Use of diaphragm with contraceptive jelly
* Use of condoms with contraceptive foam
* Use of diaphragm with condoms (“double barrier”)

You should continue using birth control for xx months after stopping the <drug>.

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 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.>>
* << 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.>>

**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, including Attachment 1.   
  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.

**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/guardian’s signature is sufficient. If the patient is a minor delete the signature lines for adult patient. If the patient is an adult, delete the signature lines for parent/guardian.*

***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** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Parent/Guardian or Legally Authorized Representative, if applicable**  *please print* | **Signature of Parent/Guardian or Legally Authorized Representative** | **Date** |
|  |  | |
| ***Name of Minor Patient*** *please print* | ***Relationship to Patient*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)* | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Doctor**  *please print* | **Signature of Doctor** | **Date** |

***Attachment 1 is optional. Delete if not needed***

Attachment 1 – Details of project schedule and procedures