Information about expanded access use for [drugs](https://www.uvm.edu/rpo/irb-policies-and-procedures#20p2) and [devices](https://www.uvm.edu/rpo/irb-policies-and-procedures#21p1)

 **University of Vermont**

**Consent for Expanded Access (Compassionate) Use**

|  |  |
| --- | --- |
| **Title:** | This should be the same as the protocol |
|  |  |
| **Treating Physican:** | PI Name |
|  |  |
| **Sponsor:** | List all agencies, companies, and other Universities that are supporting this research. If internally sponsored, list the department. Do not list the sponsor here until you have obtained funding. |

For studies involving children or cognitively impaired dependents, please include this statement-Throughout this document “you” refers to “you or your child or the person you are representing.

Your doctor, Dr. [Name], is offering to treat you for your [describe the disease/condition] under this expanded access treatment program.

**Information About This Expanded Access Treatment Program**

* Expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment when no comparable or satisfactory alternative therapy options are available.
* While this use involves an investigational product, this is not a research study.
* [Name of unapproved drug, device, or biologic] is not approved by the Food and Drug Administration (FDA) for your condition and therefore this use is experimental.
* The purpose of this form is to help you understand how [drug/device] works to give you an opportunity to decide whether you want us to use it to treat you. We may also give you information, from the company that supplies the [drug/device].
* While you are taking the [drug/device], we will tell you if we learn any new information that may cause you to change your mind about allowing this expanded access use.
* Whether or not you get this treatment is up to you.

**Specific Information About the Treatment**

* [Provide relevant background information that explains why this expanded access treatment is being recommended for this patient for their condition.]
* [If applicable, provide currently approved products and treatments for the specific condition and why those are not recommended.]
* [Describe how the drug is given, e.g., intravenously or by mouth. Provide an estimate of how long the drug may be given and name the dose to be used. If additional monitoring is required during administration of this drug (beyond standard clinical care), describe, e.g., extra blood tests.]

**Risks and Discomforts**

* [Describe side effects in lay language.]
* [Include] It is possible that new, unanticipated, different, or worse symptoms will result from using this drug/device. [If applicable, include: The drug/device can also hasten death.]
* [Include as applicable.] If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be minor inconvenience or may be so severe as to cause death.

**Benefits**

* There is no guarantee that you will benefit from this expanded access treatment.

**Costs to You**

* [Explain if the patient will be charged for the investigational medication/device and if there are any other costs related to receiving this investigational drug or device, e.g., extra laboratory tests
* If the [drug/device] treatment makes you sick or causes you injury, no form of compensation is available. Medical treatment will be provided at your expense or at the expense of your health care insurer, which may or may not provide coverage. If you have any questions about these costs or what out of pocket expenses you may be responsible for, please talk to your doctor and/or your insurance company.

**Privacy**

* Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information.
* Data regarding the treatment may be submitted to [name of the manufacturer]. The FDA and [the name of the manufacturer] reserve the right to review those parts of your medical records that are relevant to the use of the [drug/device]. These representatives are required to keep your identity and medical record information confidential.

(Note: a research HIPAA Authorization is not required because this does not meet the HIPAA definition of research, it is treatment.)

**Questions**

* If you have questions, concerns, complaints, would like to withdraw from treatment, or think the treatment has hurt you, you can talk to your doctor at [insert name and contact information].
* This treatment is subject to oversight by the University of Vermont Institutional Review Board. If you have questions about your rights or any unresolved questions, concerns, or complaints, contact them at irb@uvm.edu or you may call 802-656-5040.

**Signature**

* Your signature documents your permission to take part in this experimental treatment.
* Participation is voluntary and you may refuse treatment or withdraw from treatment at any time without penalty or prejudice to your present and/or future care.
* You will receive a copy of this document. Copies will also be stored in a separate confidential file and may be entered into your regular University of Vermont Medical Center medical record.

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Signature of Patient Date

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Name of Patient Printed

I certify that the nature and purpose, the potential benefits and possible risks associated with the [drug/device]and its proposed clinical use have been explained to the above individual and that any questions about this information have been answered.

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

Physician Signature Date

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

Physician Name Printed

Name of Physician:

Address:

Telephone Number: