VA Emergency Use of an Investigational Drug or Device

Consent Document

***DIRECTIONS FOR USE OF THIS TEMPLATE:***

* ***Do not add the footer for the approval stamp. The IRB does not stamp Emergency Use Consent Documents.***
* *Replace bracketed items in the header, such as “[Title of Study]” with the requested information.*
* *Read guidelines for each section, complete as applicable for your project and then delete the template guidelines.*
* *Example text may be used if needed but should not be italicized. Instructions in red font should be replaced or deleted.*
* *Phrases such as “I understand…” or “You understand…” are not appropriate and should not be included in the document.*
* *The document should be written at an appropriate grade level for the group of patients. Most word processors include the ability to assess the reading level.*
* *It must be clear to the patient that the data from an emergency use may not be reported in a way that implies that the activity was a prospectively planned systematic investigation designed to develop or contribute to generalizable knowledge.*

**BACKGROUND**

Include a description of the emergency use drug or device and describe why it is being used. Describe why current therapies are not satisfactory and why an alternative treatment or approach will be used. Language in the emergency use consent form must reflect that the treatment is not FDA-approved and the treatment is an option for treating the patient’s life-threatening condition. The consent form must state that the patient is not receiving treatment as part of research.

***Example****: You are being asked to allow the use of a <<drug/device>> called <<insert name of drug or device>>****.*** *This consent form explains how the <<drug/device>> will be used. Please read it carefully and take as much time as you need. Please ask questions at any time about anything you do not understand.**We will explain what other treatment could be given other than the <<insert drug/device name>>. You should understand those options before you sign this form.

The Food and Drug Administration (FDA) has not approved the use of <<insert name of drug or device>>. Doctors are studying <<insert drug or device name>> to provide treatment for patients who have problems with <<insert name of disease or injury>> and who have failed other treatments. You will not be included in these studies because you do not qualify and because this is an urgent situation. But we can use <<name of drug or device>> in your case because you have <<name of disease or injury>> and you have not improved with available treatments.*

**CONFLICT OF INTEREST**

If there is any real or apparent conflict of interest by investigators where the procedure will be performed, these conflicts must be disclosed.

**PROCEDURES**

Include a description of the procedures that will be followed chronologically using lay language, short sentences, and short paragraphs. Provide a timeline description of the procedures that will be performed, all hospitalizations, and all outpatient visits. Tell that patient how long their participation will last.

Add information regarding pregnancy testing for women of childbearing potential, if required. Indicate the frequency of pregnancy testing.

***Example****: If you agree to the use of <<insert name of drug or device>>, you will <<describe procedures>>. Your expected treatment time will be <<enter timeline>>.*

**RISKS**

**State that the emergency use drug/device has not been approved by the FDA for this use**. Include a description of any reasonably foreseeable risks, discomforts, or side effects the patient may experience for each procedure and drug (including likely results if the treatment should prove ineffective). List all side effects, no matter how rare, that are life altering or potentially life altering.

***Example****: Because <<insert name of drug or device>> is not fully studied or approved by the FDA, we do not know all of the side effects it can cause. Below are the risks and side effects that have been seen in other patients.*

*<<Describe risks, including reproductive risks. If reproductive risks are of concern, list the acceptable methods of birth control for this procedure. Describe what action will occur in the event of pregnancy (i.e., follow-up of pregnancy outcome, removal of the device, discontinuing the drug, etc.>>*

*You may feel some side effects that are not listed above. You should talk to the doctor if you feel any known or unknown side effects.*

**BENEFITS**

This section should describe the benefits to the participant which may reasonably be expected from the drug or device. The description of benefits to the patient should be clear and not overstated to avoid coercion. If no direct benefit is anticipated, that should be stated.

***Example****: We cannot promise any benefits if you receive this treatment. However, possible benefits include <<list benefits>>.* *We hope that this treatment will help you. However, this cannot be guaranteed.*

**ALTERNATIVE PROCEDURES**

Describe any alternative procedures or courses of treatment that might be advantageous to the participant. To enable a rational choice about participating, patients should be aware of the full range of options available to them.

***Example****: If you do not want to receive this treatment, there are other choices such as <<list alternatives>>, or you may choose to not receive this treatment.*

**CONFIDENTIALITY**

Describe the procedures used to maintain the confidentiality of the records and data pertaining to the patient, how the patient’s privacy will be protected and who may inspect the records. If you are collecting social security numbers, inform patients of this fact. Tell patients whether they can withhold their social security number and still participate. If the treatment is subject to FDA regulation, a statement must be included that notes the possibility that the FDA may inspect the records. If this procedure is conducted at the University of Utah and the VA, a statement must be included that this is a multi-site undertaking that combines VA data with non-VA data, and the location (i.e. University of Utah or VA) where data will be stored.

***Example****: We will keep all records that identify you private to the extent allowed by law. Records about you will be kept <<indicate how records are kept, e.g. locked in filing cabinets, on computers protected with passwords or encryption, etc.>>. Only those who work with us or are performing their job duties for <<the University, the VA, Primary Children’s Hospital, etc.>> will be allowed access to your information.*

***Example****: Representatives from <<insert name of group(s) e.g. FDA, NIH, DHHS, sponsor, etc.>> may inspect and/or copy the records that identify you. We will do everything we can to keep your records private, but cannot guarantee this.*

***Example:*** *This procedure is being conducted at the VA and the University of Utah. Information about you will be shared with University personnel. The information will be stored at the <<insert location, e.g. University of Utah, VA>>.*

If HIV testing is performed as a result of participation, state that additional consent will be required for the VAMC (as applicable) which describes how results will be given to the patient and the methods or opportunities patients will be given for appropriate counseling and medical care.

If testing is performed as a result of participation for any communicable or infectious diseases reportable by Utah State law is performed as a result of participation, the following must be addressed in this section (refer to <http://health.utah.gov/epi/report.html> for a current list of Utah’s reportable diseases):

* Tell the patient about the state reporting.
* Describe how results will be given to the patient to comply with state reporting requirements.
* Describe the methods or opportunities patients will be given for appropriate counseling and medical care.

If any photographs, videos, and/or audio recordings will be taken or obtained, the following items must be addressed:

* Describe how and what multimedia will be taken.
* Describe how the multimedia will be used.
* State whether the multimedia images/recordings will be disclosed outside of the VA. If the images/recordings will be disclosed outside the VA, this must be included in the HIPAA Authorization document, as well.

**PERSON TO CONTACT**

Explain whom patients should contact for answers to any questions, complaints, and concerns about the emergency use drug or device or related matters. Include the name of the P.I. and a telephone number with 24-hour availability. Names of co-investigators may be included as well. If the 24-hour number is a pager or the hospital operator, include further instructions for contacting the investigator.

Include specific information as to whom the patient should contact in case of a drug or device-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted. If applicable, provide information about who to contact if the patient has questions about the billing of costs for the drug or device.

**INSTITUTIONAL REVIEW BOARD**

Include the following statement verbatim:

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a recipient of an investigational treatment. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

**DRUG OR DEVICE-RELATED INJURIES:**

Include the following statement verbatim:

If you are injured as a result of the use of *<<insert name of drug or device>>*, the VA can provide you with medical care.

**VOLUNTARY PARTICIPATION**

State that participation is voluntary. Indicate that refusal to participate will involve no penalty or loss of benefits to which the patient is otherwise entitled. Also indicate that the patient may discontinue participation at any time and still receive the same standard of care that he or she would otherwise have received.

***Example****: It is up to you to decide whether or not you will receive this treatment. If you decide to take part you will be asked to sign this consent form. If you decide to take part you are still free to stop at any time and without giving a reason. This will not affect the relationship you have with the investigator or staff nor standard of care you receive. If you decide to stop, please contact the investigator so that appropriate arrangements can be made for your withdrawal.*

**COSTS TO PARTICIPANTS**

Include an explanation as to whether any compensation is available. Costs related to the drug or device should be explained. If applicable, state that the patient may want to check whether their health insurance will cover certain costs. When costs will be billed to either the patient and/or the insurance company, statements such as “*will be billed to you or your insurer in the ordinary manner”* are preferred. Include a statement that veteran-patients will not be required to pay for care received as a participant in a VA research project except as follows: Certain veterans are required to pay co-payments for medical care and services provided by the VA. Veterans receiving medical care and services from the VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services.

***Example****: All costs associated with this drug/device will be billed to you or your insurance company in the ordinary manner. Your insurance company may not pay for the costs associated with this <<drug or device>>. Therefore, these costs <<state who will be responsible e.g. “will be your responsibility” or “will be paid by the sponsor” or “the sponsor has agreed to pay $XX”, etc.>>.*

***Example****: The parts of your care that would normally be done as standard treatment such as <<list procedures or refer to the procedures identified as standard of care in the “Procedures” section>> will be billed to your insurance company.*

***Example****: A veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.*

If patients must bear any additional costs (e.g. transportation, time away from work, health costs, etc.) it must be disclosed in the informed consent information. Any such costs must be consistent with Federal laws concerning veterans' eligibility for medical care and treatment. Indicate if the patient will receive payment of any kind (i.e., money, gift certification, etc.) for participation in this study.

**CONSENT:**

Please include a consent statement written in first person such as the following:

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| --- |
| **I confirm that I have read this consent document and have had the opportunity to ask questions. I will be given a signed copy of the consent form to keep.** **I agree to receive this treatment as you have explained in this document.**  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient or Authorized Representative’s Signature | \_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of Person Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Person Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_Date |