Humanitarian Use Device

VA Consent Document

***Note to the Investigator:*** *Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.*

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

* ***Do not adjust the bottom margin or use the footer.*** *Do not delete the watermark fields in the footer.*
* *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 participants. Most word processors include the ability to assess the reading level.*
* *The words “study” or “research” should not be used, since HUD projects are not considered research.*

**DESCRIPTION OF RESEARCH BY INVESTIGATOR**

**BACKGROUND:** Include a description of the HUD and describe why it is being used. Describe why current therapies are not satisfactory and why an alternative treatment or approach will be used. Include a statement that the FDA has approved the device for humanitarian use.

 ***Example****: You are being asked to allow the use of a HUD called <<insert name of HUD>>****.*** *This consent form explains how the 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 HUD. You should understand those options before you sign this form.

The Food and Drug Administration (FDA) has approved humanitarian use of <<insert name of HUD>> to provide treatment for patients who have problems with <<insert name of disease or injury>> and who have failed other treatments. You are eligible to use <<name of HUD>> 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 physicians 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.

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 HUD>>, you will <<describe procedures>>. Your expected treatment time will be <<enter timeline>>.*

**RISKS:** **State that the HUD has not been proven effective for this use**. Include a description of any reasonably foreseeable risks, discomforts, or side effects the participant 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.

**REPRODUCTIVE RISKS:** If there are reproductive risks, please include a section which includes the following:

1. State that there may be unforeseeable risks to the participant (or to the embryo or fetus) if the participant is or becomes pregnant during their participation.
2. List the acceptable methods of birth control for this procedure.
3. Describe what action will occur in the event of pregnancy (i.e. follow-up of pregnancy outcome, removal of the device, etc.)

**BENEFITS:** This section should describe the benefits to the participant which may reasonably be expected from the device. The description of benefits to the participant 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 device. However, possible benefits include <<list benefits>>.* *We hope that this device 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, participants should be aware of the full range of options available to them.

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

**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 participants of this fact. Tell participants whether they can withhold their social security number and still participate. If the procedure 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 Medical Center, 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 study participation, state that additional consent will be required for the VAMC (as applicable) which describes how results will be given to the participant and the methods or opportunities participants 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 participant about the state reporting.
* Describe how results will be given to the participant to comply with state reporting requirements.
* Describe the methods or opportunities participants 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 FOR QUESTIONS AND DEVICE-RELATED INJURY:** Explain whom participants should contact for answers to any questions, complaints, and concerns about the 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 participant should contact in case of a 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 participant has questions about the billing of costs for the device.

**INSTITUTIONAL REVIEW BOARD:**

Include the following statement verbatim: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a HUD device recipient. 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.

**MEDICAL TREATMENT OR COMPENSATION FOR INJURY**

Include the following statement verbatim: If you are injured as a result of the use of <<insert name of HUD>>, 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 participant is otherwise entitled. Also indicate that the participant 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 device. 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 withdraw 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 withdraw, please contact the investigator so that appropriate arrangements can be made for your withdrawal.*

**UNFORESEEABLE RISKS:** State that receiving the device may involve risks to the participant which are currently unforeseeable.

***Example****: In addition to the risks listed above, you may experience a previously unknown risk or side effect.*

**RIGHT OF PHYSICIAN TO WITHDRAW:** Describe foreseeable circumstances under which the participant’s participation may be terminated by the physician without regard to the participant’s consent. Describe any anticipated circumstances for which participation may be terminated without consent and procedures required for an orderly termination of participation.

***Example****: The doctor can withdraw you without your approval. Possible reasons for withdrawal include <<list reason(s) why the participant may be withdrawn>>.*

**COSTS TO PARTICIPANTS:** Costs related to the device should be explained. If applicable, state that the participant may want to check whether their health insurance will cover certain costs. When costs will be billed to either the participant and/or the insurance company, statements such as “*will be billed to you or your insurer in the ordinary manner”* are preferred.

***Example****: All costs associated with this 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 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.*

**NEW INFORMATION:** Include a statement that significant new findings will be provided to the subject.

**Example**: *“New information may become available about the device that is being used. If this happens, your doctor will tell you about it.*

**NUMBER OF PARTICIPANTS:**

The following statement can be included verbatim: A humanitarian use device is one which is used for conditions or diseases which typically affect fewer than 4000 people in the United States per year.

NOTE: The following sections may not apply to your study. If not applicable, you can delete these headings and sections.

**CONSENT:**

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

|  |
| --- |
| 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 device, as you have explained in this document.** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant’s Signature | \_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of Person Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Person Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_Date |

**A witness signature block may be inserted here if required by the sponsor or it appropriate for the participant population. Sample witness signature statements are included below. Delete this section if you do not plan to use a witness to the consent process/signature.**

**SAMPLE #1:**

**WITNESS STATEMENT:**

The participant was unable to read or sign this consent form because of the following reason:

[ ]  The participant is illiterate

[ ]  The participant is visually impaired

[ ]  The participant is physically unable to sign the consent form. Please describe:

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[ ]  Other *(please specify)*:

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I confirm that I was present as a witness for the consent process. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to receive the Humanitarian Use Device (HUD).

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

Name of Witness

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

Signature of Witness Date

**SAMPLE #2:**

**WITNESS STATEMENT: (For Non-English Speaking Participants Only)**Consent was obtained from the participant using a short form for non-English speakers.  The short form is available in the participant’s language and this (long) consent form was read to the participant using an interpreter.

As a witness, I confirm that I was present for the complete consent process.  I confirm that the participant named above was read the information in this consent document in a language he/she understands and that the participant has agreed to receive the Humanitarian Use Device (HUD).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Name of Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                        \_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Witness                                                                       Date

**IMPORTANT: This signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block if it has been explained in the new study application (subject to approval by the IRB). Delete this if you do not plan to enroll participants using an LAR.**

**If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:**

**LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:**

I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Participant’s Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant’s wishes cannot be determined, what is in the participant’s best interests. I will be given a signed copy of the consent and authorization form to keep.

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

Name of Authorized Personal Representative

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

Signature of Authorized Personal Representative Date

Indicate the legal representative’s authority to act for the individual:

[ ]  Spouse

[ ]  Adult (18 years of age or over) for his or her parent

[ ]  Individual with power of attorney

[ ]  Guardian appointed to make medical decisions for individuals who are incapacitated