

## Humanitarian Use Device Consent and Authorization Document

### **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 HUD Proposed Use Study]” with the requested information.**
- **Read guidelines for each section, complete as applicable for your project, the proposed use 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/patients(s). 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.**

**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 humanitarian use device HUD (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.*

**PROCEDURES:** Include a description of the procedures that will be followed chronologically, including a description of any screening procedures, the HUD procedure, any patient follow-up visits, tests or procedures. Use 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.

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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/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: The FDA has approved humanitarian use of this device, which means that it has not yet been proven effective for this use.

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**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/patient (or to the embryo or fetus) if the participant/patient is or becomes pregnant during the procedures described in this consentir 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/patient which may reasonably be expected from the device. The description of benefits to the participant/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 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/patient. To enable a rational choice about participating, participants/patients 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.

**PERSON TO CONTACT FOR QUESTIONS AND DEVICE-RELATED INJURY:** Explain whom participant/patients should contact for answers to any questions, complaints, and concerns about the device or related matters. Include the name of the physician/P+ and a telephone number with 24-hour availability. Names of co-investigator/physicians may be included as well. If the 24-hour number is a pager or the hospital operator, include further instructions for contacting the investigator/physician.

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Include specific information as to whom the ~~participant~~patient 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~~patient 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~~physician. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

**DEVICE-RELATED INJURIES:**

Include the following statement verbatim:

If you are injured as a result of the use of <<insert name of HUD>>, the University of Utah can provide you with medical care. However, you and/or your insurance company will be billed for the costs of treatment. Neither the University of Utah, nor the FDA, nor the government has any program that would pay the costs of the complications of the procedures required or for the use of <<insert name of HUD>>.

**VOLUNTARY PROCEDURE PARTICIPATION:** State that ~~the procedure~~participation is voluntary. Indicate that refusal to ~~undergo the procedure with the HUD~~participate will involve no penalty or loss of benefits to which the ~~participant~~patient 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 not to take ~~part~~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 physician-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~~patient which are currently unforeseeable.

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

**RIGHT OF INVESTIGATOR TO WITHDRAW:** ~~Describe foreseeable circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's~~

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~~consent. Describe any anticipated circumstances for which participation may be terminated without consent and procedures required for an orderly termination of participation.~~

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

**COSTS TO PARTICIPANT/PATIENTS:** Costs related to the device should be explained. If applicable, state that the participant/patient may want to check whether their health insurance will cover certain costs. When costs will be billed to either the participant/patient 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 patient 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 PARTICIPANT/PATIENTS:**

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 8,4000 people in the United States per year.

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Include the Authorization and Confidentiality information as outlined:

Signing this document means you allow us, and others working with us to use some information about your health for this treatment.

This is the information we will use and include in your medical records: **Modify the following list as appropriate – delete or add items as necessary.**

- Demographic and identifying information like <<name, address telephone number, and email address>>
- <<Social Security Number – Tell participants whether they can withhold their social security number and still participate>>

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- Related medical information about you like *<<family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results>>*
- All tests and procedures that will be done as part of the HUD procedures in the study

**How we will protect and share your information:**

- We will do everything we can to keep your information private but we cannot guarantee this. Information will be kept in a secured manner and electronic records will be password protected. Information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- In order to conduct this procedure and make sure it is conducted as described in this form, the records may be used and reviewed by others who are working with us ~~on this research~~:
  - Members of the *<< insert appropriate institution(s) e.g., University of Utah Health Sciences Center, Primary Children's Hospital, Shriners Hospital >>*;
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
  - The Food and Drug Administration (FDA), who has approved this as a Humanitarian Use Device

~~Modify the list below as appropriate—delete or add items as necessary. The examples below are suggestions and may be used as applicable.~~

- ~~Other local hospital(s) that we are working with: <<list VA Salt Lake City Health Care System or any other local hospitals where information could be shared>>~~
- ~~Other academic research centers we are working with: <<list all other academic centers including those at the University that may not be within UUHSC, and explain their roles in project>>~~
- The study sponsor: *<<Name of sponsor>>*
- A research coordinating office: *<<Name of group or company>>*
- *<<Name of federal oversight agencies, i.e. the Food and Drug Administration, Centers for Disease Control, etc.>>*
- *<<Name any other groups that will receive data>>*

- Include this statement if you will share PHI outside of the University of Utah Health Sciences Center, Primary Children's Hospital, the VA Salt Lake City Health Care System, and/or Shriners Hospital: If we share your identifying information with groups outside of *<< insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children's Hospital, Shriners Hospital >>*, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again

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~~with others not described in this form.~~

- ~~Include this statement if you will not share PHI outside of the University of Utah Health Sciences Center, Primary Children's Hospital, the VA Salt Lake City Health Care System, and/or Shriners Hospital. If we share your information with groups outside of << insert appropriate institution(s) e.g., University of Utah Health Sciences Center, Primary Children's Hospital, Shriners Hospital >>, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.~~
- ~~If testing is performed as a result of the HUD procedure participation for any communicable or infectious diseases reportable by Utah State law, 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/patient about the state reporting.~~
  - ~~Describe how results will be given to the participant/patient to comply with state reporting requirements.~~
  - ~~Describe the methods or opportunities participant/patients will be given for appropriate counseling and medical care.~~
- ~~If you do not want us to use information about your health, you should not agree to receive this Humanitarian Use Device (HUD). If you choose not to receive the HUD participate, you can still receive health care services at << insert appropriate institution(s) e.g., University of Utah Health Sciences Center, Primary Children's Hospital, Shriners Hospital >>.~~

**What if I Decide to Not ~~Participate~~ Receive the HUD after I Sign the Consent and Authorization Form?**

Your decision to receive this device is voluntary. You can tell us at any time if you decide you don't want the device and your doctor will discuss options for your treatment. You can also tell us in writing if you don't want us to collect or use health information about you.

This authorization does not have an expiration date.

**CONSENT:**

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

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

**I agree to receive this device and authorize you to use and disclose health information about me, as you have explained in this document.**

Participant's Printed Name of Patient

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\_\_\_\_\_  
Participant's Signature of Patient Date

\_\_\_\_\_  
Name of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Signature of Person Obtaining Authorization and Consent Date

**A witness signature block may be inserted here if required by the sponsor or it appropriate for the participant/patient 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/patient was unable to read or sign this consent form because of the following reason:

- The participant/patient is illiterate
- The participant/patient is visually impaired
- The participant/patient is physically unable to sign the consent form. Please describe:

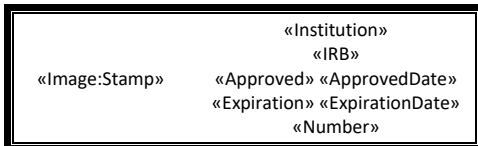
\_\_\_\_\_  
\_\_\_\_\_

Other (please specify):

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

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

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



Signature of Witness

Date

**SAMPLE #2:**

**WITNESS STATEMENT: (For Non-English Speaking Participant/Patient Only)**

Consent was obtained from the participant/patient using a short form for non-English speakers. The short form is available in the participant/patient's language and this (long) consent form was read to the participant/patient using an interpreter.

As a witness, I confirm that I was present for the complete consent process. I confirm that the participant/patient named above was read the information in this consent document in a language he/she understands and that the participant/patient 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 participant/patients using an LAR.**

**If the participant/patient 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/Patient's Name

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

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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

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