Institutional Review Board
THE UNIVERSITY OF UTAH

HUMANITARIAN USE DEVICE (HUD) INFORMED CONSENT CHECKLIST

The University of Utah requires that full informed consent and documentation of consent be obtained when treating or diagnosing a patient with an HUD. The convened board may consider exceptions to the requirement of full informed consent and documentation of consent on a case-by-case basis. The requirements of consent are not the same as those for research. This checklist may be used by physicians to ensure the consent includes the necessary disclosures.

Informed Consent for Humanitarian Use Device

	Yes	No
Is there a description of the HUD and why its use is being proposed? *Example:* *You are being asked to allow the use of a humanitarian use device (HUD) called [name of HUD] to provide treatment for patients who have problems with [name of disease or injury] and who have failed other treatments. Humanitarian Use Devices are used for conditions or diseases which typically affect fewer than 8,000 people per year.* *The Food and Drug Administration (FDA) has approved humanitarian use of [name of HUD]. You are eligible for treatment with this HUD because you have [name of disease or injury] and you have not improved with available treatments.*	☐	☐
Is there a statement that the FDA has approved the humanitarian use of the device but that it has not been proven effective? *Example:* *The FDA has approved humanitarian use of this device, which means that it has not yet been proven effective for this use.*	☐	☐
Is there a description of the procedures to be followed (screening, HUD procedure, any follow-up visits, tests, etc.)?	☐	☐
Is there a description of any foreseeable risks or discomforts to the patient including reproductive risks, if applicable? Any potential risks from the medical procedures necessary to administer the device should be included, if appropriate.	☐	☐
Is there a statement that the HUD procedure may involve risks to the patient that are currently unforeseeable? *Example:* *In addition to the risks listed above, you may experience a previously unknown risk or side effect.*	☐	☐

Is there a description of any benefits to the patient which may reasonably be expected from the device? *Example:* *We cannot promise any benefits if you receive this device. There is a chance that the HUD may (1) improve . . ., (2) reduce . . ., etc. We hope that this device will help you. However, this cannot be guaranteed.*	☐	☐
Is there a disclosure of any alternative procedures or courses of treatment? *Example:* *If you do not want to receive this device, you can discuss with your doctor any other options, such as not seeking treatment.*	☐	☐
Is the necessary contact information provided for questions and device-related injury? Explain who patients should contact for answers to any questions, complaints, and concerns about the device or related matters. Include the name of the physician and a telephone number with 24-hour availability.	☐	☐
Is the Institutional Review Board contact information included? *Standard language:* *Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a patient receiving treatment as described in this consent. Also, contact the IRB if you have questions, complaints, or concerns which you do not feel you can discuss with the physician. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.*	☐	☐
Is the device-related injuries statement included? *Standard Language:* *If you are hurt from the use of the humanitarian use device (HUD), you can choose to get medical care at the University of Utah. The University of Utah has not set aside any money to pay the costs of this medical care. The University will work with you to try to address any medical costs.* *Costs will be charged to you or your insurance company (if you have insurance). Costs can also be charged to others who may have responsibility for paying for your medical care.* *Since your care involves the use of an HUD, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with the HUD.* *The University of Utah is a part of the government. If you are hurt from the use of the HUD and want to sue the University and its employees and students, special laws may apply.*	☐	☐

The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government and limits the amount of money a person may recover. You can review sections 63G -7-101 to -904 of the Utah Code.		
Is there a statement that the procedure is voluntary? *Examples:* • *It is your choice whether to be treated with the humanitarian use device. If you choose not to be treated with the device, it will not result in a penalty or loss of benefits to which you are otherwise entitled.* • *It is up to you to decide whether you will receive this device. If you decide not to take part in this treatment, it will not affect the relationship you have with the physician or staff, or the standard of care you receive.*	☐	☐
Is there a description of any costs to the patient? The costs the patient is likely to incur and that insurance may not cover all costs should be explained as fully as possible. Because the coverage of treatment with the HUD could be complex, it may be appropriate to recommend that the patient consult their insurer about reimbursement before initiating the treatment. *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 will be your responsibility.*	☐	☐
Is there a statement regarding significant new findings? *Example:* *New information may become available about the device that is being used. If this happens, your doctor will tell you about it.*	☐	☐
Is there a statement describing the confidentiality of records? Information about confidentiality of the clinic/hospital should be included and may be combined with an authorization section. *Standard authorization language:* *The University of Utah will restrict access to your personal information in compliance with applicable privacy laws and regulations. Staff members of the University of Utah, [insert additional as appropriate], and the Food and Drug Administration may access, receive, inspect, or copy your information. Additionally, your health insurers, health care providers, and anyone you have given permission to access your medical records may learn of your treatment. For more information about how the University of Utah uses and discloses protected health information, please review our Notice of Privacy Practices.* *If you stop treatment, information that was already collected in connection with this treatment may still be shared with FDA. If the result of this treatment is published, your personal identifying information will not be used. Although it is unlikely to*	☐	☐

happen, there is a possibility that your personal information may be accidentally disclosed.		
Is the language used in the consent process understandable to the patient(s)?	☐	☐
Are research-related terms absent from the document? • "research" (can use "treatment" or "procedure" instead) • "investigator" or "PI" (can use "physician" or "doctor" instead) • "research participants" (can use "patient" instead)	☐	☐

Signatures

	Yes	No	N/A
Is there a consent statement included? *Example:* *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 the procedures described in this consent and authorize you to use and disclose health information about me, as you have explained in this document.*	☐	☐	
Is space included for the patient (or parent) to print their name, sign, and date the form?	☐	☐	
Is space included for the person obtaining consent to print their name, sign, and date the form?	☐	☐	
If applicable, is the Legally Authorized Representative signature block included?	☐	☐	☐

Revisions: