Institutional Review Board
THE UNIVERSITY OF UTAH

EXPANDED ACCESS INFORMED CONSENT CHECKLIST

Full informed consent and documentation of consent must be obtained when treating a patient using expanded access. 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 Expanded Access of a Drug or Device

	Yes	No
Is there a description of the expanded access (e.g., a statement that the patient does not have any FDA-approved product available for them for treatment)? *Examples:* • *For your condition, there is no drug approved by the Food and Drug Administration (FDA) for use in routine medical care in the United States.* • *The Food and Drug Administration (FDA)-approved drug or drugs available for your treatment did not work for you.* • *You cannot tolerate the side-effects of the drug or drugs approved by the Food and Drug Administration (FDA) for treatment of your condition.* • *The Food and Drug Administration (FDA) has not approved the use of this device for treatment of your condition.*	☐	☐
Is there an explanation of the purpose of treating the patient using expanded access? Depending on the different types of expanded access, the explanation may vary. *Examples:* • *Your doctor would like to treat you with [name of drug]. [Name of drug] is an investigational drug. It is not approved by the FDA for treatment of your disease. However, for your case, your doctor has [asked for permission from the FDA; received permission from the FDA] to treat you under the FDA's expanded access program.* • *Your doctor would like to treat your condition by using [name of device]. The [name of device] has not been approved by the FDA. However, for your case, your doctor has [asked for permission from the FDA; **or** received permission from the FDA] to use the device under the FDA's expanded access program.*	☐	☐
Is there a description of the procedures associated with the treatment (procedure/treatment, 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 drug/biologic/device, should be included, if appropriate. Instructions for whom the patient should contact if experiencing serious side effects may also be appropriate to include.	☐	☐

	Yes	No
Is there a statement that the treatment or procedure may involve risks to the patient that are currently unforeseeable or unknown? *Example:* *There may be side effects of this treatment that we do not know about. These effects could be immediate and short term, or your future health may be affected in ways that we currently do not understand.*	☐	☐
Is there a description of any benefits to the patient which may reasonably be expected from the investigational drug/device? *Examples:* • *There is a chance that the investigational [drug/device] may (1) improve . . ., (2) reduce . . ., etc. However, there is no guarantee that it will happen in your case.* • *Your doctor would like to treat you with the investigational [drug or device] because [he/she] believes that it may benefit you. However, there is no guarantee that you will benefit from this investigational treatment. It is possible that you will receive no benefit other than receiving the standard care (regularly seen by a doctor, evaluated for your condition, etc.) associated with receiving this treatment, or it could worsen your condition.* • *We do not know if this investigational [drug/device] will help you. Your condition may get better, stay the same, or possibly get worse.*	☐	☐
Is there a statement about what other choices the patient may have? To provide an investigational drug/biologic under expanded access, the doctor should determine there is no available comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. It should be explained that the doctor has made such a determination. *Examples:* • *Your doctor has determined that there are no other [drugs/devices] approved to treat your disease.* • *There are no other [drugs/devices] approved for your disease or clinical trials that you could enroll in. However, you can discuss other options with your doctor, such as [not taking any investigational drug/not seeking further treatment].*	☐	☐
Is the necessary contact information provided for questions about treatment (including injury) and an emergency contact, if appropriate? Explain whom patients should contact for answers to any questions, complaints, and concerns about the drug/biologic/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 expanded access treatment as described in this consent.*	☐	☐

	Yes	No
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 treatment or device-related injuries statement included? *Standard language:* *If you are hurt from being in this expanded access treatment, 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 this is expanded access treatment, 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 this expanded access treatment.* *The University of Utah is a part of the government. If you are hurt in this expanded access treatment 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 treatment or procedure is voluntary? *Examples:* • *Whether or not you take this investigational drug is up to you. If you choose not to receive the investigational drug, it will not result in penalty or loss of benefits to which you are otherwise entitled.* *You can choose to take the investigational drug now but change your mind later. Tell your doctor right away about your decision if you change your mind later. It will not result in any penalty or loss of benefits to which you are otherwise entitled.* • *It is your choice whether to be treated with the investigational device. If you choose not to be treated with the investigational device, it will not result in penalty or loss of benefits to which you are otherwise entitled.*	☐	☐

	Yes	No
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 an investigational drug/biologic or device could be complex, it may be appropriate to recommend that the patient consult their insurer about reimbursement before initiating the treatment.	☐	☐
Is there a statement regarding significant new findings? *Example:* *During your treatment, if we learn any new information about the risks or benefits of the [name of investigational drug or device], your doctor will let you know.*	☐	☐
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" should not be used (can use "treatment" or "procedure" instead) • "investigator" or "PI" should not be used (can use "physician" or "doctor" instead) • "research participants" should not be used (can use "patient" instead) • **NOTE:** The term "investigational drug" or "investigational device" may be used because the drug or device has not been approved and the FDA is allowing access to the patient outside of a clinical trial. You do not need to remove or revise the term "investigational drug" or "investigational device".	☐	☐

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: