Expanded Access Template Document

Individual Patient Expanded Access Informed Consent Template

This template should be used as a template for the informed consent when treating a patient under an Indvidiual Patient Expanded Access program.

Expanded Access for a Single Patient -
[Insert title]

You are being asked to take part in this expanded access program of [drug/device] because you have [describe disease state]. This program is voluntary and includes only people who choose to take part. Expanded access programs (EAPs) are a way that certain investigational [drugs/devices] can be made available outside of a clinical trial (research study). An "investigational" [drug/device] is a [drug/device] that is still being tested to find out whether it's safe and effective and is not yet approved for sale by the U.S. Food and Drug Administration (FDA). This program will only involve a single subject. It is being done because there are no other acceptable options for the treatment of your disease.

Please read this consent form carefully and take your time making your decision. As your doctor or staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to receive [drug/device]. The nature of this procedure, risks, inconveniences, discomforts and other important information are listed below.

[*Insert here if there are any investigator and/or institutional conflicts of interest that should be disclosed*]

WHO WILL BE MY DOCTOR?

If you agree to receive [drug/device], Dr. [insert name] will be your doctor and will be in contact with your regular health care provider throughout the time that you are in the expanded access program and afterwards, if needed. If you have any problems with [name of drug/device], you should contact Dr. [insert name]'s office.

WHY IS THE USE OF THE INVESTIGATIONAL [DRUG/DEVICE] BEING OFFERED?

The investigational [drug/device] is being offered to you because the comparable [drug/devices] that are available and have received FDA approval may not be appropriate to use for your condition. You are not in a study; however, information about your experience with [drug/device] may be shared with others as explained in the "WILL MY INFORMATION BE KEPT CONFIDENTIAL?" section.

HOW MANY PEOPLE WILL TAKE PART?

One person will take part in this program at XXX, though other patients may receive similar treatment in the future.

WHAT IS INVOLVED IN PARTICIPATING IN THIS PROGRAM?

[Describe drug administration/device implantation procedures here.]

For devices only:
If you agree to have the device placed, it can remain in place as long as it is working properly and there are no complications that require removal.

Monitoring
You will be monitored for the duration of treatment with [drug/device].This will include: [List via bullet point any activities that are required due to participation in this program and not done as SOC]

Follow-Up Visits
You will return for the following clinic visits and activities: [List via bullet point any activities that are required due to participation in this program and not done as SOC]

All of the above tests will be used by the doctor to see how well [drug/device] is working. This follow-up schedule may be different from and may be in addition to the standard of care.

WHAT ARE THE RISKS OF THE PROCEDURE OR DRUG/DEVICE?
If you choose to receive [drug/device], the known potential risks will be discussed with you by Dr. [insert name]. Risks that you may experience are described below:
[bullet point risks]

[Refer to your institution's consent template and add standard language as appropriate for pregnancy testing and contraceptive measures, depending on the age/gender/condition/ disease of the subject]

ARE THERE BENEFITS TO THIS PROGRAM?
If you agree to receive [drug/device], there may be direct medical benefits to you, but this cannot be guaranteed. You may experience [list possible benefits].

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WHAT ALTERNATIVES ARE THERE TO THE [DRUG/DEVICE]?
Dr. [insert name] will discuss with you the available treatment options. If you decide not to receive [drug/device], your decision will not affect your care at your institution. You will continue to receive standard clinical care at your institution.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in this program may involve some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this program and may be seen by people including those collaborating, funding, and regulating the program. We will share only the minimum necessary information in order to conduct the program. Your personal information may also be given out if required by law.

Once you sign and date the consent form, the medical team working on this expanded access [drug/device] will collect information about you.

By agreeing to receive [drug/device], you are authorizing access to your health information that is protected by law ("Protected Health Information"). This includes all information collected during the clinical care described in this consent form and health information in your medical records that is relevant to your care.

As part of agreeing to receive [drug/device], the doctors and staff will record health information about you that contains your name and other personal identifiers. Limited data which does not directly identify you may be made available to FDA, national and foreign regulatory agencies, health or other governmental authorities.

Records regarding your involvement in this expanded access program will be maintained while you are in the program and for at least two years after you have discontinued the program.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?
You or your insurance agency may be responsible for all costs of care, including the cost of the [drug/device] used. The study team will discuss this with you before you make a decision about you receiving the [drug/device]. You may also wish to contact your insurance representative to discuss this further before making your decision about receiving [drug/device].

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[*For investigational drug or device if patient will be responsible for ALL costs:*
(charging the patient requires prior FDA approval):]
You or your insurance will be responsible for the cost of all care associated with the procedure[*s*] and the [drug/device] itself. This includes the cost of treatment if the [drug/device] makes you sick or causes you injury. It is possible that your insurance will not pay for the cost of the [*include as applicable: drug, device, procedure to implant the device*, *or tests or procedures that are required for you to get the drug/device*] because the [drug/device] is considered investigational. If that occurs, you will be responsible for all costs, and these costs may be substantial.

[*For investigational drug or device if sponsor is providing free drug/device:*]
The [drug/device] will be provided to you at no cost. You or your insurance company will be responsible for the remaining costs related to this treatment, including the cost of treatment if the [drug/device] makes you sick or causes you injury. You will be responsible for any costs your insurance does not cover. Please note that your insurance is not obligated to pay for any care including tests, procedures or treatments consequent to the use of [drug/device], unless it is specifically required to do so by law or contract. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

WHAT ABOUT [DRUG/DEVICE] RELATED INJURIES?
Immediate necessary medical care is available at your institution in the event that you are injured as a result of your decision to receive this investigational [drug/device]. However, there is no commitment by your institution, or your institution's physicians or [drug/device Manufacturer] to provide monetary compensation or free medical care to you in the event of a [drug/device] related injury. Your insurance carrier will be billed for the cost of such treatment, and will be charged in the usual way.

For questions about [drug/device]-related injury, contact Dr. [insert name] at (xxx) [number] during regular business hours and at (xxx) [number] after hours and on weekends and holidays.

[If a contract with the manufacturer is involved, ORC will provide any necessary edits to this section.]

WHAT ABOUT MY RIGHTS TO DECLINE TO RECEIVE THIS [DRUG/DEVICE]?
FOR DRUGS or DEVICES:
You may choose not to receive the [drug/device], or, if you agree to receive it, you may withdraw from [receiving further drug/device] or participating in follow-up at any time. If

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you withdraw, no new data will be collected about you unless the data concerns an adverse event related to the [drug/device]. If such an adverse event occurs, we may need to review your entire medical record.

ALWAYS INCLUDE:
Your decision not to participate or to withdraw will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at your institution. If you do decide to withdraw from follow-up, we ask that you contact Dr. [insert name] in writing and let him/her know that you are withdrawing. His/Her mailing address is Insert address here.

You will be notified of any new significant findings that develop that may affect your willingness to receive [drug/device] or participate in follow-up visits.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the program or a [drug/device]-related injury or if you have complaints, concerns or suggestions about the program, contact Dr. [insert name] at (xxx) [number] during regular business hours and at (xxx) [pager] after hours and on weekends and holidays.

For questions about your rights or to discuss problems, concerns or suggestions related to the program, or to obtain information or offer input about the program, contact your institutions Institutional Review Board (IRB) Office at (xxx) xxx-xxxx.

STATEMENT OF CONSENT
"The purpose of this expanded access program, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the investigational [drug/device], or to obtain information or offer input about this expanded access program. I have read this consent form and agree to receive the investigational [drug/device], with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

____ ___________ ____________
Signature of Patient Date Time

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____ ___________ ____________
Signature of Person Obtaining Consent Date Time

[add LAR signature if applicable to patient's situation]

____ ____________ ____
Signature of Legal Representative Date Time

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