

INFORMED CONSENT

What should I look for in an informed consent form?

A prospective clinical research patient's guide to reviewing the informed consent document

In order to participate in a clinical research study, a person must give "Informed Consent." This is required by law. "Informed consent" is a process—not just a form—and this process must be ensured by any organization or individual involved in human subject research.

A general definition of "Informed Consent" as it relates to clinical research might be summarized in this way:

Informed Consent is a prospective participant's decision to participate in a clinical research trial:

- 1.) After careful deliberation of the information about the research study itself
 - a.) Purposes
 - b.) Procedures
 - c.) Risks
 - d.) Possible benefits
 - e.) Alternative procedures
 - f.) Placebo: whether or not the study includes use of a placebo*—an inactive substance given in place of a study medication)
- 2.) After all questions are answered to the satisfaction of the prospective participant
- 3.) After the prospective participant has had ample opportunity, if desired, to speak with trusted friend(s) or family member(s) about the research study
- 4.) With knowledge that he or she may withdraw from the study at any time, for any reason (or for no reason at all)
- 5.) With knowledge that no punitive actions by the study doctor or study coordinator will take place if the participant decides to withdraw
- 6.) With knowledge about a range of topics
 - a.) Privacy protections in place
 - b.) Time required to participate in the study
 - c.) Compensation
 - d.) Contact persons for questions or concerns that arise during the study (changes in health, medical emergency, patient rights)

* Placebo information will be covered in another section

The Informed Consent Process

Relationship

One part of the process is conveying information from the study doctor or study coordinator to the potential participant. This is often done in the context of a *relationship*, such as with your primary care physician or a specialist who cares for specific medical conditions. You may have been asked by your doctor to consider participating in a study that might improve the treatment of a specific medical condition.

Or, you may have read an advertisement in the newspaper about a clinical study because you have a medical condition and want the opportunity to be involved with an experimental medication or device that may help you. (We will revisit this last possibility, because you may or may not receive the actual experimental medication, depending on how the study is designed. Some studies include a group of people who receive an inactive substance, called placebo. The results of these two groups of study participants help researchers learn about the impact of the experimental medication.)

Regardless of how you were recruited for a clinical research study, *personal contact* with someone who can explain the study is an important part of the informed consent process. There is someone who will explain the purpose and goals of the study, and answer your questions.

The Informed Consent Document

A second part of the process is reviewing the informed consent form or document. This form needs to convey the following information in lay terms and simple language:

- 1.) What the study investigators expect to learn by conducting the research
- 2.) What the study will involve
- 3.) What study participants will be expected to do
- 4.) Risks and possible benefits of participating
- 5.) Whether or not any compensation for time and travel will be provided

Each of these topics will be addressed so that you will know what to look for in an informed consent form, as well as what your rights are regarding the informed consent process and study participation. This is not an exhaustive list, and you should always feel free to ask the study doctor and/or the study coordinator if you have any question or concern regarding your health or the study.

1.) WHAT DO THE STUDY INVESTIGATORS EXPECT TO LEARN BY CONDUCTING CLINICAL RESEARCH?

- What is the purpose of this study?
 - This varies by study, and you should carefully read the informed consent document. The wording of this should be as simple as possible, and lay terms should be used. Often, it is difficult to explain

complex scientific processes in simple language. Usually, the wording is at the eighth-grade reading level.

2.) WHAT QUESTIONS SHOULD I ASK?— any questions about what is in the informed consent document, or any questions that arise from participating in a study (also see a list of suggested questions at the end of this document). You have a right to have your questions answered to your satisfaction

3.) WHAT WILL THE STUDY INVOLVE?

- Do I have to participate in this research study?
 - No. You have the right to choose whether or not to participate.
- If my primary care physician or specialist is conducting the research, and if I don't want to participate in the study, do I have to find another doctor?
 - No, your decision not to participate will not affect your regular medical care. If, however, the study is being conducted by a clinical research site, rather than a regular medical practice, you will not be able to receive ongoing medical follow-up there unless you are a clinical research participant.
- What are the inclusion and exclusion criteria?
 - This varies by study. Read the informed consent form carefully. Show the form to trusted friend(s) or family member(s), if you would like another opinion. Consult your primary care physician, if he or she is not conducting the study, and request an opinion.
- How many appointments will I have? How long will they be?
- What specific procedures will take place during the study?
- Will there be any pain or discomfort from the procedures?
- If there is any pain or discomfort associated with the procedures, what type of relief is offered, if any?
 - Note: While blood-draws and injections, or removal of ECG pads may be uncomfortable, they are usually brief enough to be tolerated by most people, and pain-relief agents are not used. Please tell the study doctor if you have any concerns about the pain or discomfort associated with a study procedure.

4.) WHAT DO I HAVE TO DO DURING THE STUDY?

- Will I be able to take my prescribed and over-the-counter medications during the study?
 - This varies by study, so ask the study doctor.
- If there is an experimental medication or device used in this study, do I have to pay for it? Will my insurance company be billed for it?
 - Usually, the study drug or device will be paid for by the pharmaceutical company that develops it.
 - Some studies look at medications that you already take as a normal part of your medical care. In these studies, since you or your

insurance company would normally pay for the medication, there may be no subsidy from the pharmaceutical company for your current medicines.

- WHAT IF I CHANGE MY MIND AND DON'T WANT TO BE IN THE STUDY ANYMORE?
 - You are free to withdraw from a study at any time, for any reason, or for no reason at all.
 - Some medications should not be stopped immediately, but they should be tapered over a period of time. Your study doctor will advise you, and provide information about what to do if you want to withdraw from the study. A procedure for withdrawal from a study should be spelled out in the informed consent document.
 - You should not experience any negative consequences personally for choosing to withdraw from the study.
 - Unless the research is being conducted at a research-only facility, you may continue to receive medical follow-up after you withdraw from a study.
 - Research-only sites do not follow patients for ongoing medical care. Once a patient finishes or withdraws from a study, the patient is no longer seen by the study doctors affiliated with that site.
- WILL I BE REQUIRED TO USE BIRTH CONTROL? Will my spouse or partner be required to use birth control?
 - This varies by study, and your personal beliefs should be respected.
 - However, declining to use an acceptable form of birth control during some studies may exclude you from participation. This is because of the requirement to protect unborn children from possible birth defects.
- WHAT HAPPENS IF I/MY SPOUSE/MY PARTNER BECOMES PREGNANT DURING THE STUDY?
 - Usually, if a woman becomes pregnant while enrolled in a clinical study, she is withdrawn from the study, and the study doctor monitors her pregnancy with the physician who is responsible for her pregnancy care.
 - As well, the study doctor will want to monitor the health of the infant for some time after birth.
 - If this is not addressed in the informed consent document, you should ask your study doctor directly.

5.) WHAT ARE THE RISKS AND/OR POTENTIAL BENEFITS OF PARTICIPATING?

- What side-effects or other health risks are known about the medication being studied?
 - There are risks associated with all medications. Sometimes, the risk is minor. Other times, the risk is as significant as death. You should be advised of risks, and the likelihood of experiencing the risk, based on past research.

- It is possible that little is known about the likelihood of risks. Some risks are not known until well after a medication has become available for general use.
- Some risks are temporary and non-debilitating, such as a rash or mild nausea. Other risks are sustained and life-threatening. Carefully read the informed consent document and ask the study doctor about this part of the informed consent form.
- Side-effects are a type of risk. Some side-effects can be minimized by taking certain precautions, such as taking the study medication with food, to minimize stomach upset. This is not the case for all study medications, and you should ask the study doctor what to do if you think you are experiencing a side-effect to the study medication.
- Will I definitely receive the study medication, or is there a group of participants who will receive placebo (inactive substance)?
 - In some studies, called “double-blind” studies, one group of participants receives the study medication and the other group receives an inactive substance that looks, smells, and feels like the study medication. Neither the study doctor nor the participant knows which of the two (active medication or placebo) he or she is receiving. This allows researchers to learn the impact of the study medication by comparing the results of the two groups of participants.
- Who will see my study records? Who will have access to personal information about me?
 - Your study records will be kept separate from your regular medical record. Your study doctor and the study staff will share them only as required by law, such as to any oversight organizations (FDA or Department of Health & Human Services, for examples), the study sponsor’s monitoring personnel (to ensure compliance with the study requirements), and under certain circumstances, the Institutional Review Board (IRB) that provides oversight to ensure that your rights are protected.
 - You will be assigned a study identification number. When studies are completed, reporting of results does not include any information that would identify you, personally.
 - The Health Insurance Portability and Accountability Act of 1996 requires that medical practices disclose how they handle patients’ protected health information within the medical records. You should have signed a HIPAA authorization form for your primary care physician and all other physicians or health care organizations involved with your care.
 - If you have any concerns or additional questions about your medical record’s privacy, please share these with your study doctor or study coordinator.
- What are the possible benefits to participating in this study?
 - There may be no direct benefit to you for participating in a study.
 - You may experience an improvement in your symptoms.

- There may be unknown benefits, just as there are unknown risks, associated with participating in a research study.
- You might feel good that you may be helping others with the same medical condition.

5.) WILL I BE COMPENSATED FOR PARTICIPATION IN THIS STUDY?

- Will I be compensated for participation in this study? If so, how much?
 - You may or may not be compensated for participating in a study. Study doctors are not allowed to offer “coercive” amounts of money to participants, and the amount of compensation is reviewed by the Institutional Review Board (IRB).
 - Participants who are economically disadvantaged may need financial assistance with travel to and from appointments. If you have difficulty with accessing transportation or paying for meals (when study procedures are done over several hours, for example), please inform your study doctor or the study coordinator about possible reimbursement.
- When will I receive the compensation?
 - This varies from study to study. You may receive compensation at the end of each study visit, or you may not receive compensation until you complete the study.
 - If you withdraw from the study, you will probably receive pro-rated compensation for all visits completed.
 - In general, you should not have to wait until all patients have completed the study to receive your compensation.

Questions and Answers to ask yourself when considering the Informed Consent Form:

Q: Are there words in the informed consent form that I do not understand?

A: If so, ASK the study doctor or study coordinator to explain or define the concepts or words that are unclear.

Q: What if my questions are not answered to my satisfaction?

A: First, make sure that you have given the study doctor and study coordinator a chance to clarify. Consider asking a trusted friend or family member to accompany you to the appointment.

Q: What if I have a complaint about the study doctor or study coordinator?

A: If you have a complaint, it is usually best to speak directly with the study doctor or study coordinator first. They are interested in you as a person, and most people prefer to have the opportunity to address a complaint themselves before a third party is involved.

Nevertheless, if you have attempted to resolve a complaint directly with the study doctor or study coordinator and have had no response or success, you should contact the Institutional Review Board contact person named in the informed consent document.

A person cannot give truly “informed” consent if the words to explain the research study and procedures are too technical, or if there is too little opportunity (or *relationship*) for questions and concerns to be addressed. Time is an element of the informed consent process, and just because an informed consent document has been signed does not mean that it is permanent. You may withdraw your consent in writing at any time. These basic points, along with the Question and Answer bullets, represent the main prerequisites of legitimate Informed Consent.