

Questions I Should Ask During The Informed Consent Process

- What is the purpose of the study and how will it affect my daily life?
- Will this study involve any painful or uncomfortable procedures?
- What will it cost me to participate in this study?
- Does this study include investigational drugs or medical devices not approved by the FDA?
- What are the known or potential risks and side effects?
- Who is responsible for monitoring my well-being and to make sure proper safeguards are being followed?
- What are my alternatives to participating in this study?
- Who is authorized and available during non-business hours (e.g., at night, during a holiday, or weekend) to help me if problems arise or should I wish to withdraw from the research?
- Can I leave a research study once I have started?

For more information about this research study contact the principal investigator at:
(put local information below)

For more information about your rights as a participant in research contact the University of Vermont's Institutional Review Board:

**The University of Vermont
Committees on Human Research
(802)-656-5040**



The University of Vermont And Fletcher Allen Health Care

THE INFORMED CONSENT PROCESS

*What You Need To
Know.....*



Fletcher Allen Health Care and University of Vermont

Human Subject Research Studies and the Informed Consent Process

What Is Informed Consent?

Informed consent refers to the voluntary choice of an individual to participate in a research study based on an accurate and complete understanding of all the details regarding their participation.

The Informed Consent Process

Informed consent is not a single event, it is an ongoing educational process that takes place between the research staff, and you, the volunteer.

The process begins with the research staff providing a full description of the research procedures and all details pertaining to the trial. The research staff have the responsibility to discuss the following with you prior to your decision to participate.

- * Purpose of the study
- * Procedures required as part of the study
- * Risks associated with study
- * Benefits to yourself and others
- * Alternative therapies if applicable
- * Anticipated duration of study participation and time requirement for visits, tests, etc.
- * Potential costs to you while participating
- * Compensation for your participation if applicable
- * Confidentiality protections that are in place for the study

- * Injury compensation policies if you are injured as a result of the study.

All of these points are included in what is referred to as the informed consent form. The research study as well as the informed consent form has been reviewed and approved by the Institutional Review Board (IRB) to ensure that the consent form includes all of the above points and that the information is conveyed in language that is understandable to you. The decision to participate in a research study is not something that should be taken lightly. You should take as much time as you need to ask questions, do some research on your own, get a second opinion or discuss with your family and physician. Any questions that you have should be addressed prior to signing the informed consent document.

Once you feel that all of your questions have been answered and are comfortable with the processes, procedures, and expectations, you will sign the informed consent document. The research staff will provide you a copy for your records.

During your participation in the study, the research staff will inform you of any new information or changes to the research that may affect your willingness to continue to participate such as:

- A new risk has been identified.
- One treatment has been proven to be better than another.
- The length of treatment may be extended beyond what was initially felt to be adequate.

- An addition of a quality of life questionnaire to assess how the treatment affects your day to day living.

When new information or changes occur you may be presented with an informational sheet, a revised informed consent form to sign, or be given an addendum to the original consent form that you would need to sign. You should completely understand and feel comfortable with the new information prior to continuing your participation in the study.

Can I Leave the Study?

Your participation is voluntary and you do have the right to withdraw your participation at any time. If you wish to withdraw, you should notify the research staff as soon as possible to assist you in discontinuing current research treatments safely. There will be no penalty or loss of benefits to you for refusing to participate or withdrawing from the research study and you will continue to receive whatever treatment is necessary for your disease or condition.

